PRESENTATIONS TO E-PEDIGREE WORK GROUP ON DECEMBER 5, 2007

- Alien Technology
- California Pharmacists Association (CPhA)
- National Community Pharmacists Association (NCPA)
- Generic Pharmaceutical Organization (GPhA)
- Three Rivers Pharmaceuticals
- TEVA
- Watson Pharmaceuticals
- PhRMA
- California Health Care Institute (CHI)
- EPCglobal
- Aegate
- National Coalition of Pharmaceutical Distributors (NCPD)
- Siemens Corporation

Pharmaceutical e-Pedigree

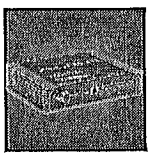
UHF RFID Considerations

Victor Vega
Director, Technical Marketing
Alien Technology Corporation

5 December 2007

CONTEXT

HURDLES / ADVANCEMENTS

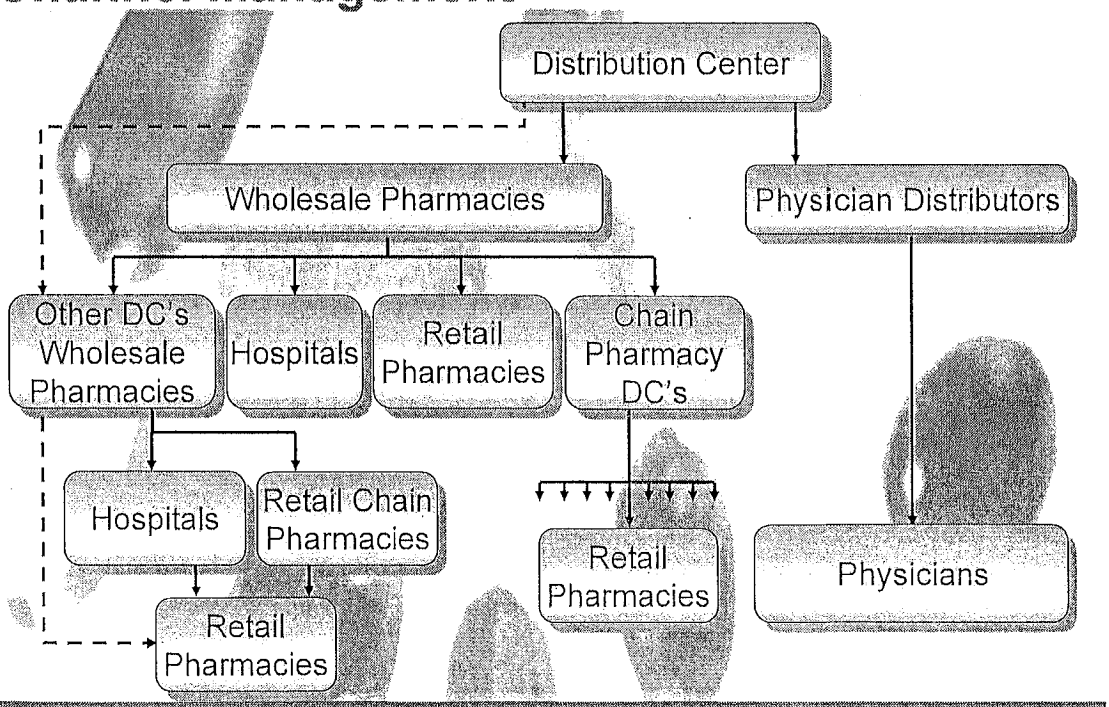


DEMO / Q & A

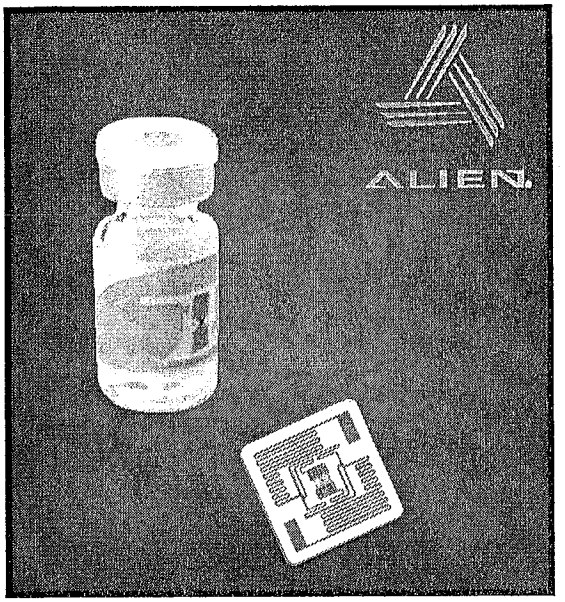
The UHF RFID industry has significantly advanced in the past few years, with substantially improved technology enhancements, healthy cost reductions, and a robust global UHF infrastructure.

In this briefing, we take a look at a few of the previous hurdles, and the recent UHF technological industry advancements.

Pharmaceutical Pedigree Channel Management



Pharmaceutical RFID Motivations



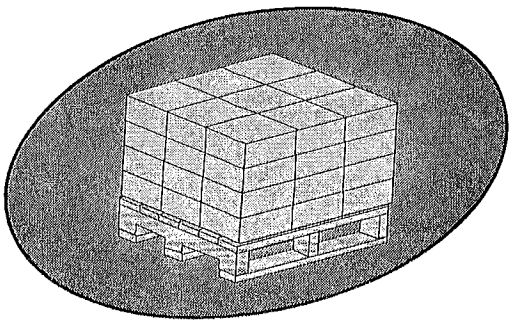
- Electronic Pedigree
- Patient Safety
- Counterfeiting
- Channel Diversion
- Inventory Management
  - Expiration / Out-of-Stocks
- FDA Endorsement
- Sample Management
- Containment
- Reverse Logistics
- Supply Chain Management
- Marketing
- >35 States considering e-pedigree legislation

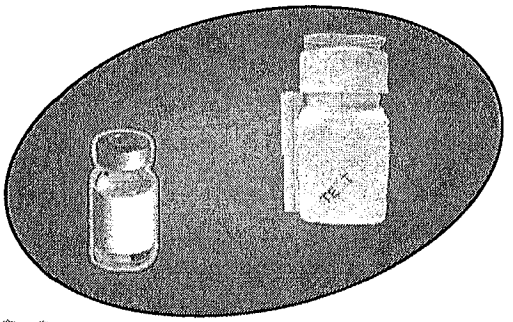
e-Pedigree Options – Item / Case / Pallet

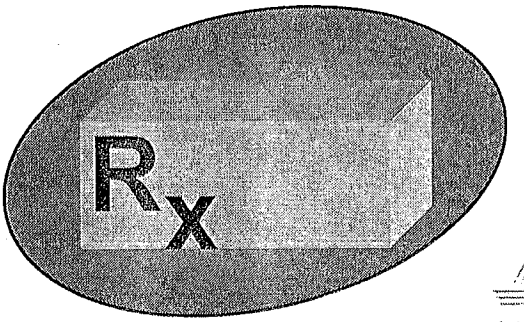
2-D Data Matrix

HF RFID

UHF RFID

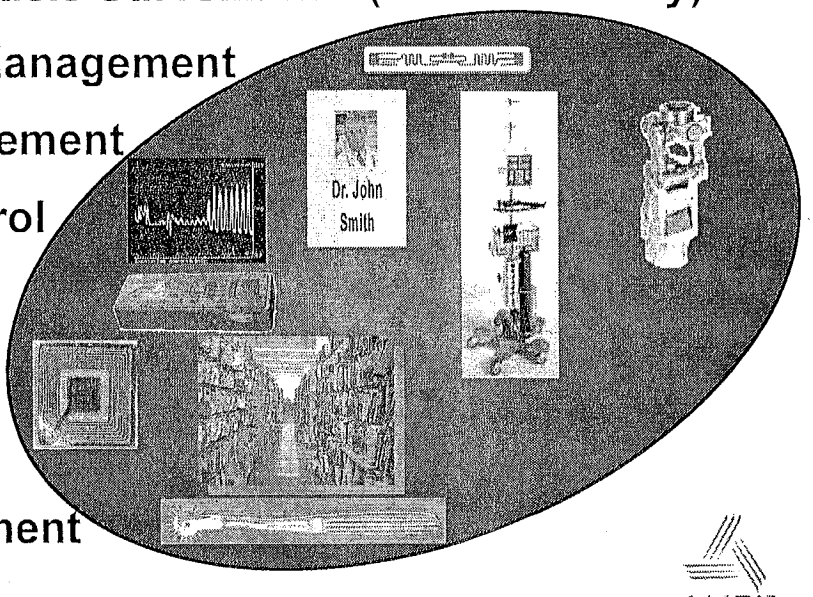






Other Wireless Infrastructure Considerations

- Electronic Article Surveillance (EAS – security)
- Cold Chain Management
- Asset Management
- Access Control
- Dispense
- Surgical
- Prosthetics
- File Management



RFID Considerations

TOPIC	DISCUSSION
RF Exposure	No notable EMI efficacy on Potency / Stability / Temperature of Biologics or pills
Challenges	Absorbent water-based content / gel-packs Limited item-level surface Small items and vial diameters Metal or foil surfaces Shadowing / Shading (close proximity of tags to one another)
Benefits	Electronic pedigree / Brand Protection Channel management Reverse logistics: Product recalls / containment Integrated born-on / expiration date code assists with first-in, first-out stock rotation. Optimize storage densities, enhance inventory management, minimize out-of-stocks Improved transportation and logistics management efficiencies
Applications	Item level vials / prescription bottles Case / bulk / pallet tracking Self dispense – (hospitals / medical offices) Cold chain temperature monitoring and recording Electronic manifest capability Smart shelf notification modes for changing inventory status
Cost	Consider cost of multi-facetted infrastructure & labor / error for line-of-site solutions

Spectral RF Considerations

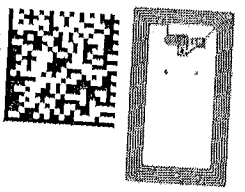
FEATURE	13.56MHz Near Field Coupling (High Frequency, HF)	915MHz Far Field Coupling (Ultra High Frequency, UHF)
RF Efficacy	No known effects (e.g. on protein biologics / pills)	No known effects (e.g. on protein biologics / pills)
Advantages	Free space read ranges typically < 1/3 meter Water based product does not significantly impede near-field magnetic coupling Mature product offerings Globally accepted frequency	Excellent free space read range, > 5-7 m Reduced read range of smaller tags on product often still exceeds optimum HF read range Simplistic, low cost tag antenna / construction Single UHF technology deployment simplifies technology / cost infrastructure Open protocol / several suppliers Fast read rates Global standard and frequency (860-960MHz) High adoption drives low pricing UHF offers both magnetic near field & electric far-field coupling.
Disadvantages	Not a viable long range solution (e.g. case/pallet) High-Q inductive resonant loops easily de-tuned Inductive bridge adds MFG complexity / cost Dual technology HF/UHF tag & reader (UHF likely for longer range, e.g. cases/pallets) will add to infrastructure cost (e.g. readers, antennas, tags, support, programmers, etc.) Typically higher relative pricing than UHF (e.g. 3x)	Absorptive water based products impede electric far-field performance, but performance often exceeds that of HF.

Multiple Technologies

UHF RFID

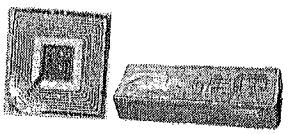
HF RFID

2-D
Data Matrix



LF RFID
Access
Control

EAS
Security



Battery Assist
Temperature Tag

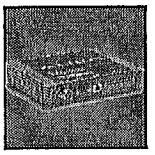
UHF

UHF RFID

Items
Cases
Pallets
Security
File Management
Access Control
Vending

CONTEXT

HURDLES / ADVANCEMENTS

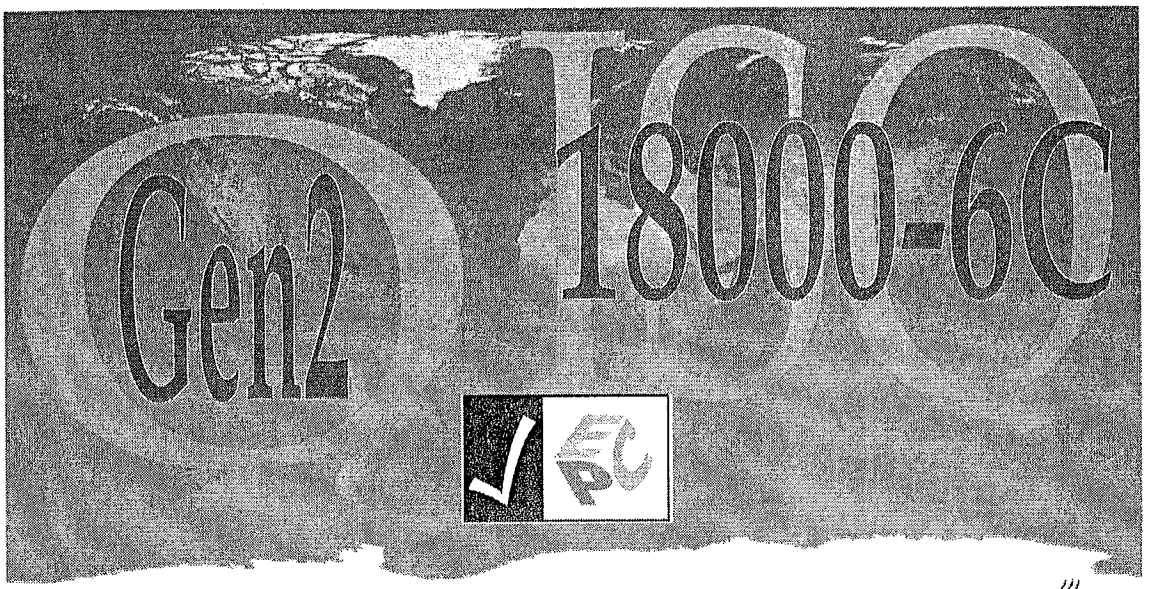


DEMO / Q & A

Technology Hurdles of the Past

- ~~Tags challenged on material other than Free Space~~
- ~~"Dumb" Readers, Unable to Filter / Mask~~
- ~~Tag Size~~
- ~~Customized Tags per Product Category~~
- ~~Tag Prices~~
- ~~Regional Tag Design Requirements~~
- ~~Reader Collision~~
- ~~Severe Tag De-Tuning on Product~~
- ~~Short Read Range~~
- ~~Wireless Access Point Contention~~
- ~~Sluggish responses~~
- ~~Limited Suppliers & Support~~
- ~~Severe Tag ESD Issues~~
- ~~Interference Susceptibility~~
- ~~Tag Shadowing / Shading~~
- ~~Unfriendly User Interfaces~~

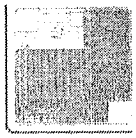
Global Standards



Adoption Barriers – Is it the Hardware?

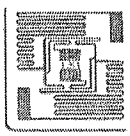
- Absolutely not
- Gen2 is globally accepted
- World Tags operate globally
- Gen2 is flexible & scaleable
- The technology is stable, robust & reliable
- 4th generation EPC hardware platforms
- 5th generation EPC Tag IC's
- Multiple IC, Tag, Reader, Antenna, software and system providers in the marketplace

Silicon Developments - Present



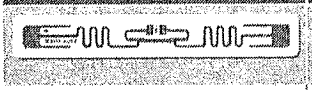
- **RFID Silicon**
  - Superior sensitivity
  - Extended user memory
  - Enhanced noise rejection
  - Vastly increased acquisition & programming speeds
- **Wide Spectral Bandwidth**
  - Alleviate regional tag incompatibility
  - Wide operational spectral band (860-960MHz)

UHF RFID Tag Developments



- **Performance / Characteristics**
  - Global Tag Designs
  - Small Item-Level UHF geometries (e.g. 0.9" square)
  - Minimal tag detuning performance degradation
  - "One-size-fits most" tag advancements
  - "***Optimal***" free space read ranges > 10 meters observed (though not practical on product)
  - E-field tag reads demonstrated on / in aqueous materials
  - Near 100% tag yields

Wide Tag Selection (many others available)

TAG	Highest Volume	Global Tag	General Purpose	Price Leader	Highest Performance	Small Item
	√√	√√	√√	√√	√	
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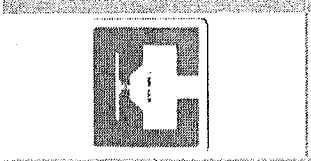	√	√	√			
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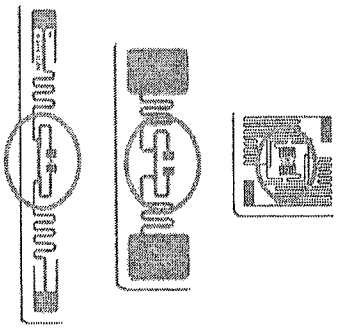
UHF Tag Anatomies

- Some UHF RFID tag antennas accommodate both Near & Far fields.
- These tags (shown) are conventional Far-field dipoles - notice the loop in the center? This serves to couple the near-field component as well.



- A UHF RFID tag with a concentrated near-field (a.k.a. magnetic-field, or inductive-field, or H-field) might look like that shown to the right. Its read range would be very short relative to the dipoles.

Magnetic loop

Tag Snapshot

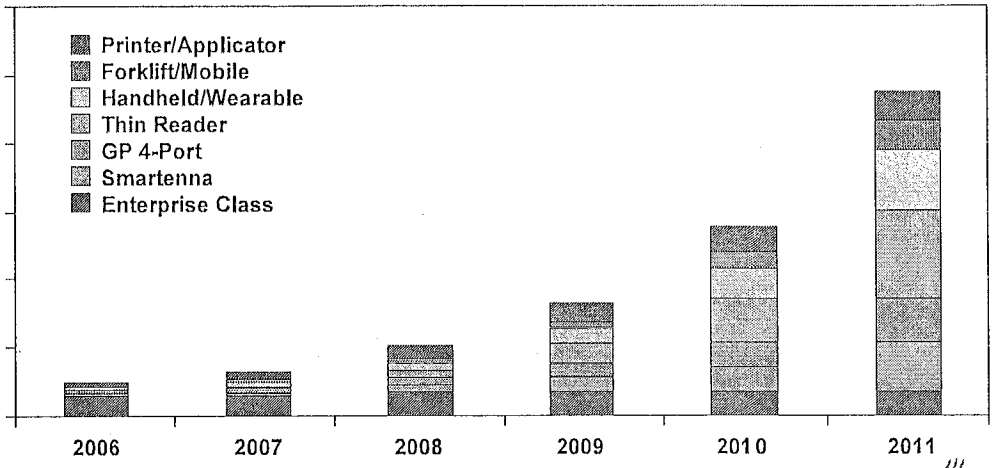
Attribute	Past	Present
Typical approximate UHF form-factors	¾" x 6", 4" x 4"	0.9" x 0.9", ¾" x 3", ½" x 4"
Memory	64 / 96 bit ePC	96 bit ePC + optional user memory (e.g. up to 512 bits)
Volume Inlet Prices	~ $1	<10¢ typical
Applications	Pallets	Cases, Pallets, Assets
Typical Optimized Free Space Read Range	1.5 – 3 meters	10-30 meters

EPC Gen2 RFID Security Overview

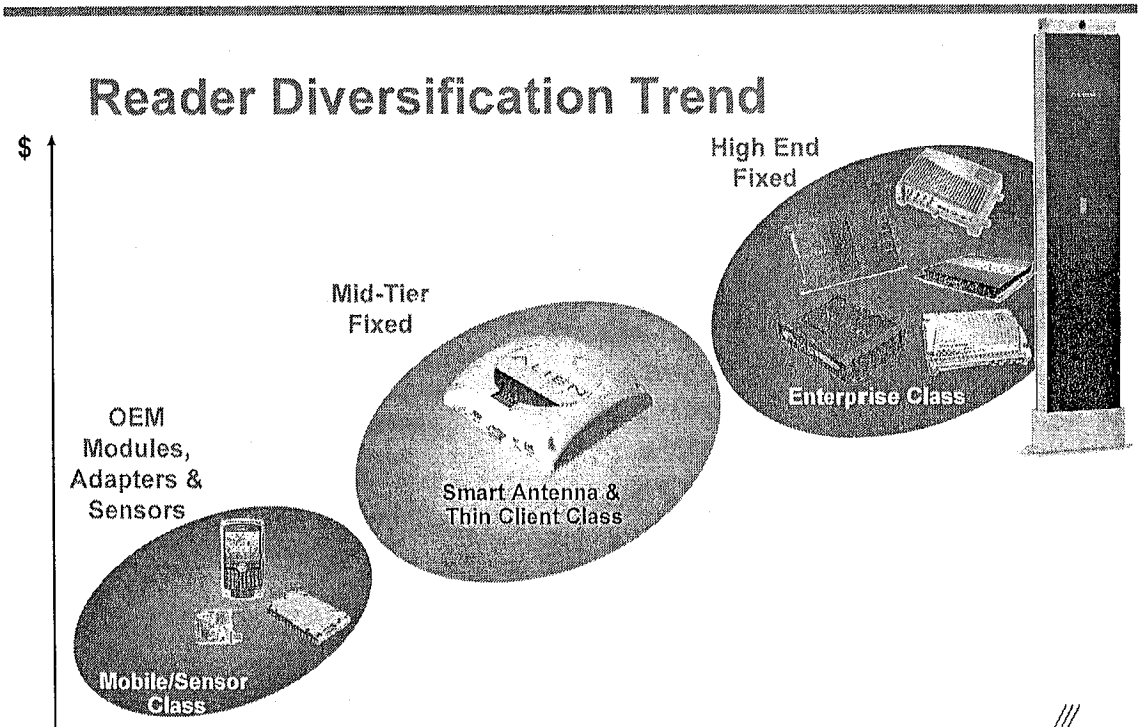
FEATURE	CONVENTIONAL RFID (e.g. ePC Class 1 Gen2)
Authentication / Counterfeit	Moderate
Duplication	Moderate Difficult with Custom TID
Memory	ePC Class 1 Gen2: 96 user bits Optional user programmable memory (e.g. manufacturer, National Drug Code (NDC), S/N, born-on / expiration date, channel & ECC authentication)
Additional Security Options	Tamper-proof label Self destruct inlay Random Item ID's with "CRC Case Tag" Custom TID Security encode/decode Key (like Access Control) 32 bit Access P/W; 32 bit Lockable Memory PermaLock option

Emerging Reader Diversity

Increasing application-specific reader embodiments



Reader Diversification Trend



Marquee Software Operating Environments

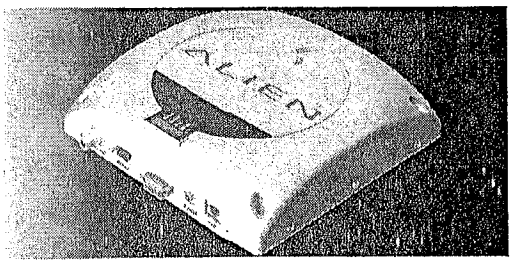
- Marquee software commitments promote strong industry stability & reinforce interoperability.

Microsoft **BizTalk RFID**

IBM **WebSphere 6.0**

ORACLE

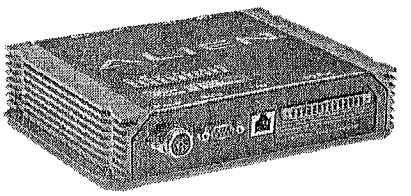
Smart Antenna Class Attributes *(ALR-9650)*



- **Simple installation**
  - Small, low profile footprint
  - Power-Over-Ethernet
  - Combined Reader / Antenna
- **Scaleable**
  - Serial and LAN connectivity
  - Optional external antenna port
  - (2) Digital Inputs and (2) Digital Outputs
  - Remote firmware and version management

High-Performance Enterprise Reader (*ALR-9900*)

- **High performance**
  - Optimized for high read success with large tag populations
  - Superior interference rejection in dense reader environments
  - Interference mitigation ("sniff & read")
- **Easy to manage**
  - Remote firmware, version, identification management
  - SNMP, configurable UDP heartbeat for reader status
  - Crisis recovery: LAN and power loss
  - Triggered network upgrades
- **Easy to integrate**
  - Small footprint (approx 8" x 8" x 2")
  - Optically Isolated GP-I/O (4 In / 8 Out)
  - Easily configurable Profile files
  - Monostatic – Single antenna per read point

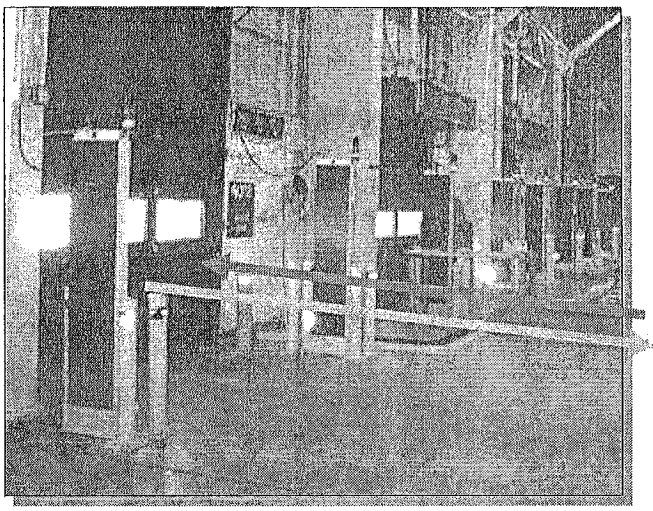


Reader Snapshot

Attribute	Past	Present
Volume Reader Prices	~$3,500	~$600 to $1,500
Optimal Free Space Read Range	2 - 3 meters (1.5 – 2 m practical)	10-30 meters (5 – 7 m practical)
Interference rejection	Terrible. 0 Interferers.	Great. 4+ interferers.
System Infrastructure	Reader, Filtering Host, Heavy Middleware, Enterprise	Reader, Middleware, Enterprise
Primary Fixed Reader Vendors	Alien, AWID, Matrix, SamSys ThingMagic	Alien, Impinj, Symbol, ThingMagic, Sirit, Omron, Intermec, etc.
Stability / Reliability	Poor.	Great.

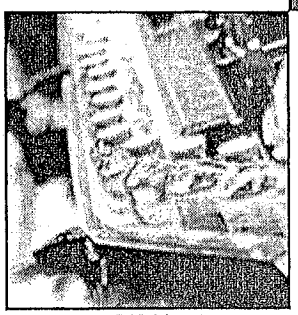
Reader Enhancements

- Direction Detection



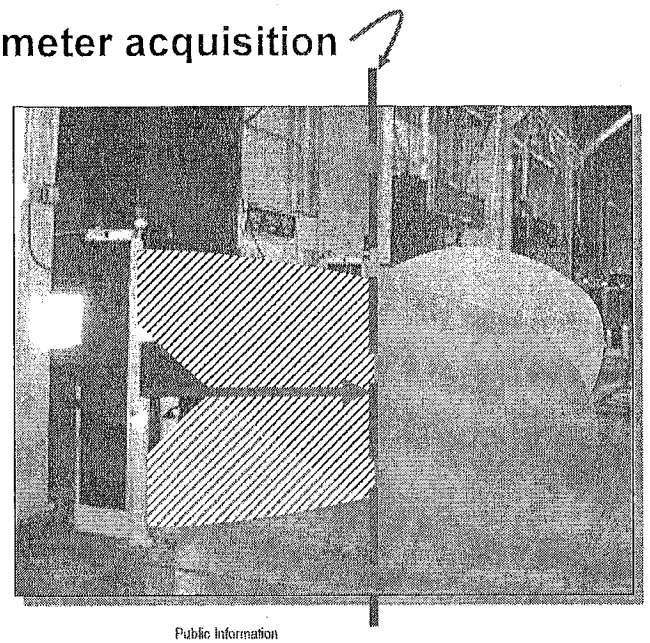
Future Reader Expectations

- Singulation / Diversion



Future Reader Expectations

- **Defined perimeter acquisition**
- Without reducing read performance margins, only process tags within a defined perimeter.



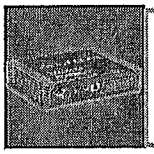
Remember – *you* (downstream partners) are driving this industry

Multiple Technologies

Simplicity

CONTEXT

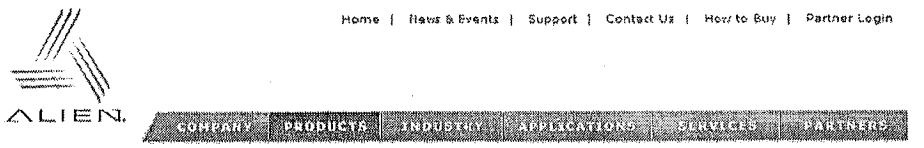
HURDLES / ADVANCEMENTS



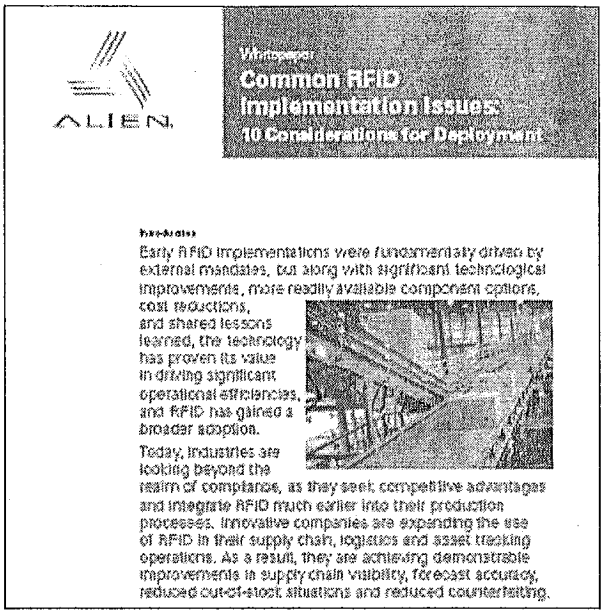
DEMO / Q & A

Additional Info (posted for 2 weeks)

http://www.alientechnology.com/whitepaperdownload/



Common RFID Implementation Issues



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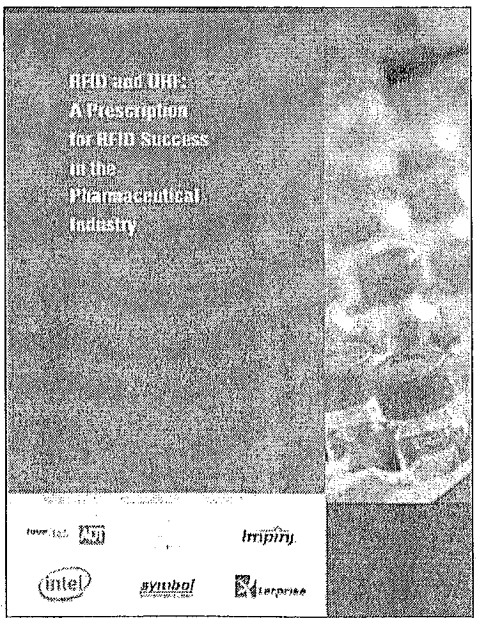
Rev A

RFID and UHF: A Prescription for RFID Success in the Pharmaceutical Industry



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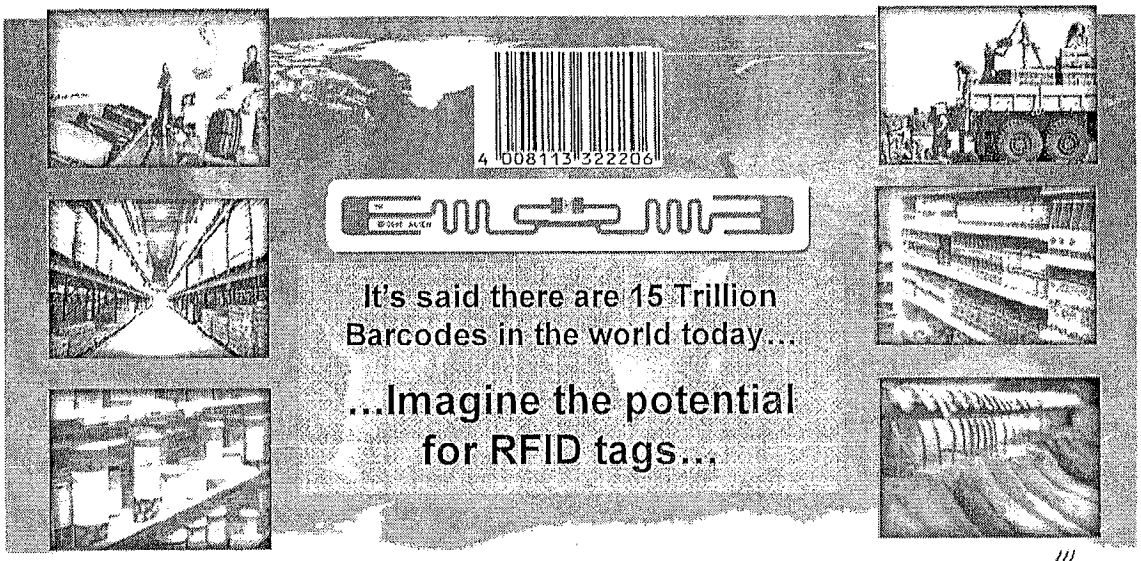
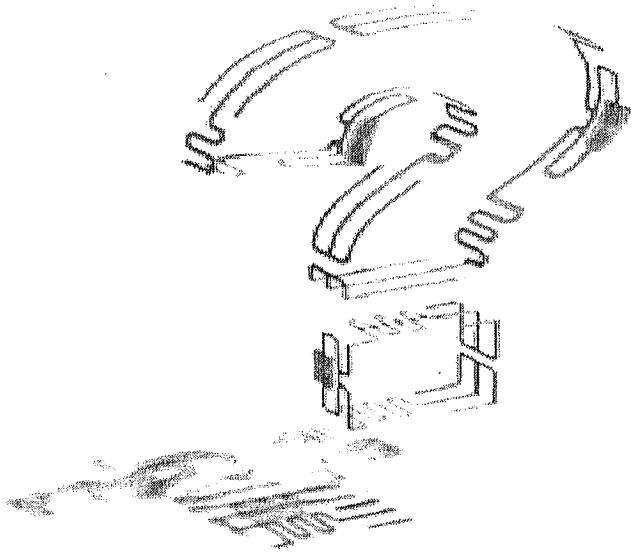
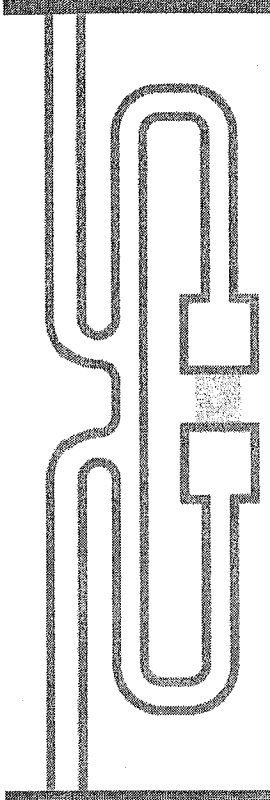
Rev A

Food for Thought



Questions?





For more information:

Victor Vega

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Website: www.alientechnology.com

White Papers (posted for 2 weeks)
http://www.alientechnology.com/whitepaperdownload/

Thank You!

ALIEN

California Pharmacists Association

Presentation for Enforcement Committee
Work Group on E-Pedigree Meeting
December 5, 2007

Kathleen Lynch, Esq.
Vice President of Government Affairs

California Pharmacists Association

- Our Members
- Their Mission
  - Integral part of the Health Care Team
  - Solution driven
  - Patient Advocates

Issues with E-Pedigree Legislation

- Timing
  - Equipment
  - Space
  - Budget
  - Training Personnel
  - Upstream Partners
- Cost
  - Estimates from various groups
- Technology
  - Interoperable

3

Issues with E-Pedigree Legislation

- Inference
  - Definition
- "Grandfathering"
  - Stock in hand on 1/1/09
  - Product received from upstream partners after 1/1/09 without pedigree
- Enforcement
  - Reliance on upstream partners
  - Last minute decisions

4

Pharmacists Working Towards Compliance

- Education on E-Pedigree
- Meetings with Wholesalers
- Participating in Pilot Programs

5

2008 Issues Facing Pharmacy

1. Implementation of Average Manufacturer Price (AMP)
2. E-Pedigree Implementation
3. Tamper Resistant Prescription Pads Requirement
4. Development of New Labeling Requirements
5. Possible Increase in Payroll taxes due to Health Care Reform
6. Drug Disposal Programs
7. Medicare Part D

6

Written Testimony of David Wilcox on behalf of the National Community Pharmacists Association before the Enforcement Committee of the California Board of Pharmacy Hearing on E-pedigree December 5, 2007 Sacramento, California

I. Introduction

Members of the Enforcement Committee (the Committee), on behalf of the National Community Pharmacists Association, I thank you for this opportunity to testify on E-pedigree issues.

NCPA represents the nation's independent pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care. In California we represent 2,215 independent pharmacies and their over 30,000 employees.

Many NCPA members are California pharmacists like me. I live in Fresno and am currently the president of PharmKee, Inc., a group of 10 pharmacies serving rural areas including Colinga, Caruthers, Easton, Lodi, Madera, San Joaquin, Mendota, Kerman and Fresno. I have been a practicing pharmacist since 1979 and am active in my community with the Chamber of Commerce, Planning Commission and the California Pharmacists Association, of which I am a former president. Serving rural patients is the primary focus of our pharmacies. We further specialize in serving the health care needs of low-income families.

II. The January 1, 2009 Implementation Deadline Should be Extended to January 1, 2011

We support the need for a safe drug chain of custody. NCPA wants to work with the Committee and the California Board of Pharmacy (Board) to facilitate a smooth transition to the new system. However, in order for independent pharmacists to obtain and maintain the E-pedigree technology, there must be a mechanism of financial support for community pharmacy to offset the monetary costs associated with implementation of an interoperable electronic system.

As you know, we are the end of the line in the drug chain of custody and are concerned that the lack of interoperability will force pharmacists to purchase multiple track and trace technologies – readers, scanners, etc. – with associated upgrades and to spend time training staff to understand and use the equipment and systems. It will also be necessary to spend considerable administrative time in our pharmacies managing any track and trace functions. None of these activities are being financed by the state. The state has, in effect, handed community pharmacy an "unfunded mandate!" At the end of the day, NCPA believes the public good is best served by implementing E-pedigree only when there is a complete, interoperable electronic system that can truly prevent, in an economical fashion, counterfeit drugs from entering the system.

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B. The E-pedigree technology is not ready -- and the public good is best served by delaying implementation

NCPA is unaware of any vendor that has the technology ready to be purchased and operated at an affordable price. More importantly, there is no evidence that the existing technology is universally interoperable. Since the California law requires that E-pedigree shall be "created and maintained in an interoperable electronic system, ensuring compatibility throughout all states of distribution" *Section 4034(a)* and certain companies are not prepared to implement E-pedigree, then by definition, there is no single, interoperable system. Therefore, anyone who tries to move or sell prescription drugs would then be in violation of the law. *Sections 4034(c), 4263(c), 4263(d), 4034(i).*

NCPA has advocated for a single, federal, standardized and interoperable system of pedigree, serialization and electronic track and trace technology at the retail level that requires only one set of equipment to facilitate. We believe that the California law largely mandates interoperability, but it can be argued that it does not explicitly mandate a single interoperable technology. The pharmaceutical industry appears to be proceeding with the understanding that multiple technologies and devices are in compliance with the law. We are concerned that enforcing the current deadline would cause too many implementation problems as a result of this situation.

The statutory matter before the Board is whether, and if so, in what manner, to extend the implementation date. Ideally, NCPA believes that the pharmacy would be the end recipient of the chain of E-pedigree custody and that E-pedigree requirements are best designed to be implemented up to the wholesaler level. We recognize, however, the state of California law and advocate two approaches that will help to successfully implement E-pedigree issues:

1) NCPA advocates a phased-in approach to meet an extended implementation date, which places priority on high-risk drugs that are most susceptible to counterfeiting and diversion. While NCPA acknowledges that phased-in implementation may not be an ideal solution, it appears that a phased-in approach is necessary. The Board must decide whether phased-in implementation would begin before or after January 1, 2011.

2) Whenever implementation begins, the requirements should become binding at the retail pharmacy level after it is mandated upstream. Additional implementation time of one year or more will help address the magnitude of the logistical, administrative, financial and quality of care issues of requiring implementation of the new technology at the retail pharmacy level.

C. The Cost to Pharmacy should be recognized and addressed in the implementation process.

As E-pedigree is implemented, independent pharmacists should be compensated for the costs associated with the purchase of multiple technologies. The costs to a retail pharmacy to comply with E-pedigree requirements are estimated to be anywhere between $10,000 to $40,000. These costs include obtaining the hardware, software and staff training necessary to administer, monitor and maintain the system as required by law. Section 4169(5).

The above-stated estimate is consistent with implementation estimates that were presented by retail pharmacies to the California Board of Pharmacy at its September meeting: Chain pharmacies have estimated initial per store implementation costs at $25,000 - $35,000 with an additional $5,000 - $6,000/year. One chain pharmacy stated that even once the plans of upstream trading partners are known, an additional 15 - 18 months would be necessary to implement E-pedigree. Another chain pharmacy projected that it would take $54 million for one distribution center covering 591 pharmacies to achieve end-to-end serialization. They, too, are hindered by the lack of preparation by upstream manufacturers. Another chain pharmacy concluded that its pharmacies cannot support multiple technologies and systems considering the scope of trading partners involved, nor can they deploy multiple technologies at each location to ensure connectivity with each trading partner. For those of us in the independent pharmacy sector the consequences are even worse because we are small businesses and do not have the resources of a national chain pharmacy.

I understand that the Committee and Board would like to receive detailed projections and analyses. We know that the Board would like to have active industry involvement in evaluating costs, such as through participation in pilot studies. To the degree that independents are able to participate in such studies, NCPA would be glad to facilitate such participation.

What concerns me, however, is the apparent acceptance of Walgreen's September statement that it is preparing a "very big catcher's mitt" to catch the variety of serialization approaches that it expects to receive. Walgreens stated their intent to adapt to the variety of serialization technologies that various manufacturers may choose to use. Independents simply cannot adapt to the variety of pedigree, serialization and track and trace technology that will be used under the current status of preparedness for implementation.

NCPA believes that it will not be in the best interest of public safety to proceed with implementation when it has been demonstrated that the undeveloped nature of the technologies falls far short of the interoperability as required by California law to be achieved in time to ensure compliance with the January 1, 2009 date. The Board has the authority to mandate an extension of the deadline, but the Board cannot by fiat say there is compliance with the law if E-pedigree is implemented without true interoperability. Not only is it good public policy to extend the implementation date, but requiring universal E-pedigree to begin without ensuring interoperability runs counter to the California law.

In 2006, the first year of implementation of the Medicare prescription drug program, 1,152 independent pharmacies in the United States were closed or sold to other companies. After five years of stability in the independent sector, we witnessed this five percent decrease in community pharmacies in just one year. The costs associated with implementing E-pedigree will be too high for some California pharmacists to absorb. This means even more small business pharmacies will be put in jeopardy. This will harm patient access to prescription drugs and consultation care.

D. Recent Federal Law is Another Reason to For the Board to Proceed Prudently to Ensure Government Mandates do not Run Ahead of Universal Standards and Technological Developments

To review, the pedigree language passed by Congress this past fall included provisions that require the FDA Secretary to develop a standardized numerical identifier "(which, to the extent

practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging . . . at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." *P.L. 110-085, Sec. 913.* The Secretary must do so by late March, 2010 (30 months after enactment).

In order to avoid the very real possibility of implementing a California standard only to face a different federal standard, it would be helpful for the Board to extend the implementation deadline to the date authorized by Section 4163.5 -- January 1, 2011. Choosing the extension does not mean that pedigree preparation should or will come to a halt. Instead, the interagency collaboration and industry consultation as mandated by the federal law will give affected parties an opportunity to work together to create a uniform system of pedigree within the confines of both the federal and California laws. NCPA would appreciate strong support by the Board for the interest of independent pharmacies and their patients in the state and federal process.

The need for careful work to harmonize the federal and California law is highlighted by the federal law highlighting RFID as a promising technology[1], even though the FDA has historically not been receptive to RFID technology. It is unknown how the Secretary will react to the most recent discussions about track and trace technology in California. E-pedigree and track and trace technologies are not a well-developed field either in terms of technological or commercial acceptance. NCPA believes there is a definite benefit to extend the deadline to allow the pharmaceutical community better opportunity to plan likely federal developments before California E-pedigree is implemented.

III. Inference

There does not appear to be a universal definition of inference. NCPA takes inference to mean that a transported container has a label that identifies the items within, but the recipient is not required to physically identify that each contained item matches up with the list of items. The recipient of the container is, however, allowed or required to "infer" that the container contains the listed items.

The California law requires that E-pedigree tracks each dangerous drug at the smallest package or immediate container distributed and received and that there must be a unique identification number established at the point of manufacture that is uniformly used.[2] Allowing for inference appears to be a concession that "smallest package serialization" is not obtainable. Where unit level serialization is not possible and inference is instead needed, NCPA does not believe that the recipient of the container – including pharmacists – should be required to receive the container and accept any liability that might arise from accepting a container whose packing list does not match the products contained therein.

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[1] *P.L. 110-085, Sec. 913, amending Chapter V of the Federal Food, Drug, and Cosmetic Act at new 21 U.S.C. 505D(b)(3).*

[2] "A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and relieved by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug." *Section 4034(d).*

"...uses a unique identification number, established at the point of manufacture... that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug." *Section 4034(i).*

NCPA questions whether true safety is adequately protected by inference. However, if the Board sees the need to have inference then a pharmacist and other recipients of "inferred" containers should be held harmless for the contents of the container.

IV. Grandfathering

NCPA supports a clean and easy to remember "grandfathering" rule – permitting non pedigree drugs manufactured before the final implementation deadline to be moved and sold up to one year after the implementation date. At that time, pharmacies should have at least a six month window in which to return any non-pedigree product to wholesalers, distributors or manufacturers for credit.

V. Conclusion

NCPA appreciates this opportunity to discuss the national interests of independent pharmacy in California E-pedigree issues. Extending the implementation date is just one step in the E-pedigree process, and NCPA looks forward to continued dialogue with the Board on these issues.

Because of the inability at this point to achieve interoperability, the costs involved, the effect on independent pharmacies and the potential for confusion and harm to patients/consumers, NCPA requests this Committee to recommend to the Board that it exercise its discretionary powers pursuant to Section 4163.5 to extend the implementation date to January 1, 2011, with additional time for pharmacy compliance.

NCPA also has the following requests:

1) that the Board only implement inference with a pharmacy hold-harmless provision
2) that "grandfathered" non-pedigree drugs may be distributed up to one year after the implementation date followed by six or more months in which to return any pre-pedigree products for credit

Generic Pharmaceutical Association (GPhA)

California Board of Pharmacy
Enforcement Committee Meeting

December 5, 2007

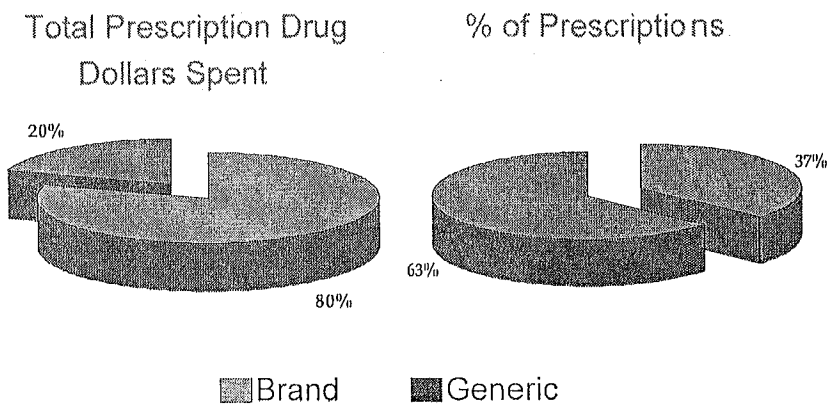
Presentation Outline

- Generic industry overview
- Anti-Counterfeit policy
- Current efforts toward compliance
- Potential impact for generic manufacturers
- Challenges to unit level serialization
- Electronic Pedigree Solution
- Summary
- Conclusions

GPhA Overview

- GPhA's members manufacture over 90% of the generic medicines dispensed in the U.S.
- Generic medicines comprise 63% of all prescriptions dispensed in the U.S., yet account for only 20% of the pharmaceutical expenditures
- Cost to consumers is 30%-80% less than the brand
- 1% decrease in generic drug utilization = $4 billion in additional healthcare costs

GPhA Overview



GPhA Position on Drug Counterfeiting

- Consumer access to safe, effective and affordable generics remains GPhA's top priority
- GPhA recognizes that introduction of counterfeit products into the U.S. supply chain would pose a serious threat to public health
- The U.S. supply chain is currently the most secure in the world
- WHO estimates that the world's drug supply is 10% counterfeit; but the U.S. drug supply is 1% counterfeit or less—FDA credits supply chain vigilance
- Support appropriate and effective measures to make the supply chain even more secure

GPhA Position on Drug Counterfeiting

- GPhA is committed to maintaining and improving the security of the drug supply chain.
  - Due to their low cost, generic drugs are not likely targets for counterfeiters
  - GPhA has requested data from FDA on instances of counterfeit generic medicine
  - To the best of GPhA's knowledge, current anti-counterfeiting measures have resulted in no instances of counterfeit *U.S. generic* medicines occurring in the normal chain of distribution in at least the past 5 years

Current Efforts to Comply with CA Pedigree Law

- A survey of GPhA members indicated that:
  - GPhA members have conducted internal cost analyses of electronic pedigree and/or serialization
  - Large and some medium sized generic manufacturers have completed or are currently in the process of conducting pilot studies
  - GPhA's economist:
    - Henry J. Kahwaty, Ph.D., Director, LECG, LLC
      1725 Eye Street, N.W., Suite 800
      (202) 446-4422

The Generic Industry Is Working to Implement Serialization

Steps taken to date include:

- Selecting and implementing solutions for e-pedigrees
- Supplying Wal-Mart with package-level serialized products for a subset of SKUs
- Soliciting proposals for packaging line and other hardware modifications, middleware, and internal or external data centers
- Developing pilots with contract manufacturers, distributors, and large retailers
- Conducting studies of optimal placement for RFID tags and determining the best RFID tags available for specific applications
- Working with vendors to convert existing serialization systems and data structures from lot-level to item-level serialization
- Working with consultants to determine best approaches to supplying serialized products

Serialization Start-up Costs

- We estimate that the start-up costs for the equipment needed to modify packaging lines will cost generic producers over $500 million
  - Cost includes only those for adding capital goods to the assembly lines (scanners, etc.)
  - Data management costs alone would exceed this amount
- There are additional start-up costs as well
  - Acquiring servers to house and process data
  - Developing or licensing middleware
  - Adjustments to shipping areas of manufacturing plants and distribution centers
  - Testing new lines, including procuring any regulatory inspections and approvals needed
  - Reviewing and modifying operating procedures
  - Packaging line downtime for construction and testing

Serialization Operating Costs

- Item-level serialization adds costs to the production of individual packages
- Serialized labels will be more expensive than those currently in use
  - Labels including RFID technology will cost between $0.25 and $0.30 more than the labels currently in use
  - Labels with pre-printed 2D barcodes will cost between $0.02 and $0.03 more than the labels currently in use
  - There are additional operating costs as well. For example, outsourcing data management can cost $0.10 or more per item
- We estimate that generic producers' operating costs will be over $300 million annually just for RFID-enabled labels

Potential Impact of Unit Level Serialization on Generics

- Unique business model:
  - Competitive commodity market; narrow profit margins on products
  - Higher volume and broader range of products than brand manufacturers
  - Regulatory variables influencing the generic market create uncertainty in timing of product launches
  - Whatever affects the generic market will have direct repercussions on public health and access to affordable medicine in California and throughout the U.S.

Potential Impact of Unit Level Serialization on Generics

- Effects on Competitiveness
  - Manufacturers unable to meet compliance by 1/1/09 will be out of business in CA this reducing the competition that results in lower generic prices
  - Participating companies will be at a competitive disadvantage in the other 49 states, unless products bound for CA could be segregated in the supply chain—not practically feasible
  - Less competition due to fewer competitors, or fewer competing products could result in higher prices

Potential Impact of Unit Level Serialization on Generics

- Several wholesalers have informed manufacturers that they expect products to be pedigreed and serialized by June or July of 2008
- Manufacturers will have to begin production of serialized products AT LEAST by May of 2008
- GPhA favors 'grandfathering' of products entering the supply chain prior to the January 1, 2009 deadline

Potential Impact of Unit Level Serialization on Generics

- Potential effects of unit level serialization on access:
  - Cost of achieving compliance will significantly increase the production cost of generic medicine
  - Large scale withdrawal from the market of low-cost/low-margin products is possible
  - Interruption of packaging lines for validation in a short period of time could result in disruptions of supply chain and/or shortages of medicine in California and throughout the U.S.

  Note: Case or pallet level serialization would be less likely to result in problems, interruptions or shortages

Potential Impact of Unit Level Serialization on Generics

- Effectiveness as Anti-Counterfeiting Measure:
  - GPhA believes that the benefits, feasibility and effectiveness of large scale unit serialization of all products is unproven and requires further investigation
  - Allowing time for pilot studies to progress and less expensive options to be explored could be more beneficial to public health

Challenges to Serialization

- A major impediment has been cost of implementation in conjunction with a lack of agreement among stakeholders on one technological standard that will support interoperability
  - Taking on the cost of experimentation is not an option for many generic manufacturers, especially small and medium sized manufacturers
- Ongoing operational costs of serialization are a based on units sold; generic medicines sell at a much lower cost and higher volume than brand; thus generic companies have much lower available price margins

Challenges to Serialization

- Major impediments to implementation and to early adoption:
  - No guidance for implementation of track and trace
    - Currently, no agreement on EPCIS usage
  - Lack of industry agreement on standards for serialization
  - The capability of software vendors to implement systems for the entire supply chain by 1/1/09 is doubtful
  - Inability of the industry to even discuss use of single technology due to federal anti-trust laws
  - Difficulty in validating databases to manage necessary information by 1/1/09
  - Patient/consumer privacy concerns
  - Lack of technical expertise broadly within the industry to implement and manage the IT infrastructure
  - Can tag vendors meet product volume demand?

Electronic Pedigree As Initial Patient Safety Measure

- Would stimulate development of infrastructure necessary to enhance track and trace capabilities
- Establish a more reliable method for authenticating shipments of product
  - Product is associated with an electronic pedigree and each change in ownership may be validated
- Would enable lot location, facilitate recalls, and enhance expiry management
- Manufacturers envision this step as feasible by the January 1, 2009 deadline

Summary

- The benefit of access to low cost generic medicine is at risk as high implementation and operational costs will raise production costs
- Challenges of implementation could reduce competition—fewer competitors and fewer competing products
- Disruptions in the supply chain may impact public health and patient safety
- Increase public sector healthcare costs

Conclusions

- GPhA encourages an industry wide review of weak points in the supply chain that allow counterfeit medicines to enter, so that strategies may most efficiently address such vulnerabilities
- GPhA will continue to work with the Board of Pharmacy and other stakeholders to implement California's electronic pedigree laws in a manner that effectively and efficiently achieves our shared objective of securing patient safety and strengthening the integrity of the supply chain

Request for Extension

- GPhA believes that industry cannot implement unit level serialization widely by 2009; additional time would allow:
  - Determination of feasibility of unit level serialization
  - Industry to ensure that standards are adequate
  - Determination of impact of costs to consumers and the healthcare system
  - Supply chain stakeholders to work towards a single, nationally acceptable system
- On behalf of the generic pharmaceutical industry, GPhA respectfully requests an extension of the deadline for implementation of California's drug pedigree requirements

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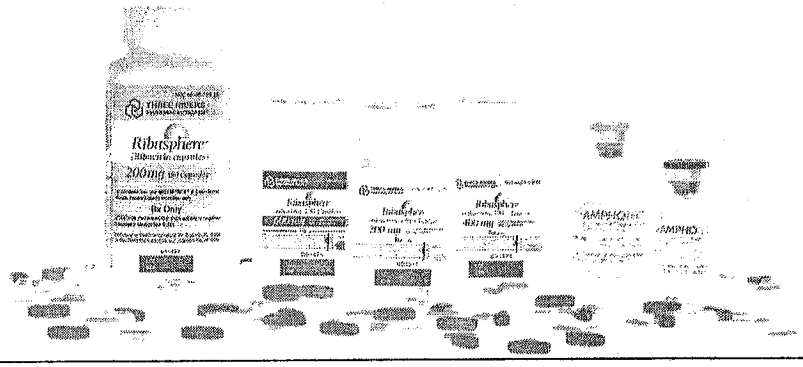
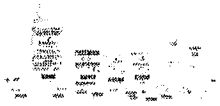
Three Rivers Pharmaceuticals



Agenda

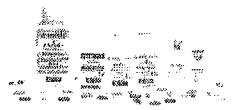
- Introduction to Three Rivers Pharmaceuticals
- ePedigree Readiness Strategy
- California Business
- Challenges
- Summary



THREE RIVERS PHARMACEUTICALS®

Three Rivers Pharmaceuticals - Introduction

- Founded in April 2000
- Started with 3 Employees - Currently 40 Employees
- Corporate Headquarters – Cranberry Township, PA
  - Sales/Customer Service
  - Accounting/Finance
  - Quality and Regulatory
  - Worldwide Distribution to over 41 countries
  - Operations/Information Technology
  - Legal/Human Resources
- Contract
  - Manufacturing/Analytical/Packaging



THREE RIVERS PHARMACEUTICALS®

Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere™ Capsules 200mg

For Combination Use with Peg-Intron (peg-interferon alfa-2b, recombinant) injection for the treatment of chronic hepatitis C in patients 18 years of age and older with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon therapy.

Ribasphere_20...

THREE RIVERS PHARMACEUTICALS®

Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere™ Tablets 200mg, 400mg, 600mg

For Combination Use with peginterferon alfa-2a for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

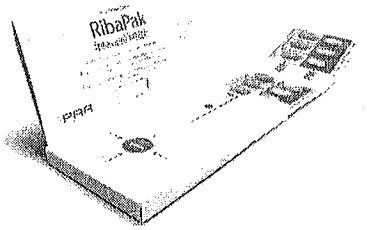
Ribasphere_tab_family

THREE RIVERS PHARMACEUTICALS

Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere Tablets RibaPak™

For Combination Use with peginterferon alfa-2a for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha.



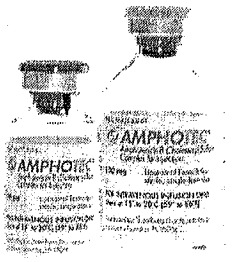
THREE RIVERS PHARMACEUTICALS

Three Rivers Pharmaceuticals – FDA Approved Products

Amphotec®/Amphocil®

50mg/100mg

Amphotericin B Cholesteryl Sulfate Complex for Injection



- **Sterile, Lyophilized Powder for Reconstitution and IV Administration**
- **For the treatment of invasive aspergillosis.**

THREE RIVERS PHARMACEUTICALS®

Pedigree Readiness Strategy

- Understand requirements and monitor the development of standards
- Work collaboratively with vendors, customers, and trading partners
- Develop standard, cost-effective solution
- Work closely with packaging vendors and software solution providers
- Integration with current validated distribution system (under 21 CFR Part 11 – Electronic Records and Signatures)

THREE RIVERS PHARMACEUTICALS®

EPCIS and Implementation – EPC Global© 2007

- How might a sample implementation work for a small company?
  1. Determine how to capture and share EPCIS business events
  2. For data capture, setup EPC readers and middleware
  3. For data sharing, make arrangements with trading partners to monitor shipments and receipts of EPC-tagged products
  4. Compile master data for the products and locations in the supply chain
  5. Setup an EPCIS data repository application with help of solution provider
  6. Load master data into the repository
  7. Route captured EPCIS events from its middleware to its EPCIS repository via the capture interface
  8. Setup subscription queries with trading partners to track shipments
  9. Enable use cases by building applications on the base EPCIS infrastructure

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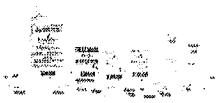
State of California

- Significant volume of specialty pharmacies
- State of California business
- Institutional business serviced through wholesalers
- State requirements will likely become national standard



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Challenges

- ePedigree initiatives will consume 100% or more of 2008 I/T Budget
- Contract vendors in FDA filing may take different approaches
- Individual compliance requirements by state and customer/trading partner

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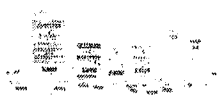
Summary

- Concern about understanding requirements
- Item-level serialization – Vendor cooperation
- Find solution which meets requirements and ensures supply chain efficiencies
- Deploy an architecture to allow for long term growth
- Patient safety and security of supply chain is a priority for 3RP



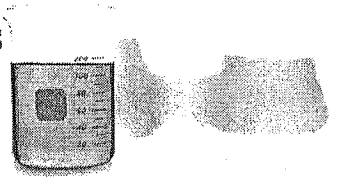
THREE RIVERS PHARMACEUTICALS®

Thank You

THREE RIVERS PHARMACEUTICALS®

Securing the Pharmaceutical Supply Chain:

A Generic Manufacturer's Perspective



California Enforcement Committee

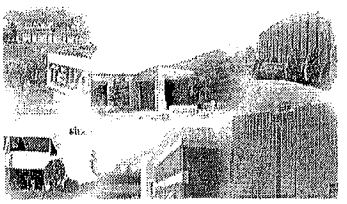
December 5, 2007

Opening Remarks

- TEVA supports the goal of securing the integrity of the pharmaceutical supply chain to ensure the provision of safe prescription drug products to the public
- TEVA is the leading generic pharmaceutical company in the world with the largest pipeline in the industry
- For the US market, TEVA ranks #1 of all manufacturers in TRxs filled
  - TEVA USA sells and distributes:
    - Over 1200 SKUs
    - Approximately 1 million saleable units of Rx drugs per day
    - Approximately 30 billion doses per year

Supply and Distribution Chain

- 16 TEVA manufacturing sites supporting the US market
  - 8 US sites
  - 8 international sites
  - 68 unique internal packaging lines
- 50 outsourced manufacturers
- 5 contract packagers
- 1 primary US distribution site
- Hundreds of ship-to points



TEVA's success depends on the prompt, seamless coordination of a very complex supply and distribution network

Current Efforts to Promote Safety

- Comply with existing federal and state-level pedigree laws
  - Require ADRs to purchase TEVA-labeled product either directly from TEVA or from another TEVA ADR
  - Pass ePedigree in other states where required
- Conform with FDA standards/cGMP requirements for drug manufacturers
  - Validate all manufacturing-related processes
  - Audit vendors of active and inactive ingredients as well as suppliers of outsourced finished product
- Participate through GPhA to promote effective federal and state laws to ensure supply chain integrity and seek standardization of related technology
- Established a corporate-wide anti-counterfeiting team to evaluate implementation of overt and covert identification technology into product and product packaging

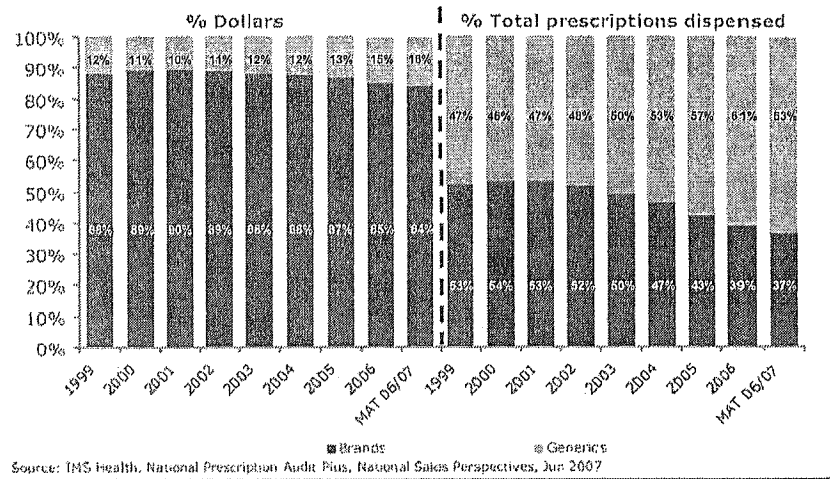
Challenges of Item-Level Serialization

- Lack of unified standards for Track and Trace interoperability
  - Risk of adopting technology that may not prevail
  - Open questions regarding ability to rely on unit/case/pallet inference
- Long Implementation Timeline
  - Identification of workable equipment and technology
  - Need to conduct pilot studies along the supply chain
  - Validation of equipment and databases
- Disruption to Ongoing Operations
  - Packaging lines will need to be shut down to retrofit
- Significantly more expensive than lot-level ePedigree

Impact on Generic Manufacturers

- The primary mission of the generic drug industry is to provide patients with high-quality, low-cost pharmaceuticals that are safe and efficacious
- The growth of generic drug utilization has saved the US public billions of dollars and has enabled some patients to receive treatment they otherwise may not have been able to afford
- The implementation of item-level serialization and track-and trace-capability will significantly increase the production cost of generic medicine
- Compared to their brand counterparts, generic manufacturers have lower revenues and profits and are therefore less capable of absorbing such costs—as a result, generic manufacturers may be forced to increase prices or even discontinue certain product lines

Generics v. Brands



Source: IMS Health, National Prescription Audit Plus, National Sales Perspectives, Jun 2007

Actions to Date

- Formation of a global, interdisciplinary project management team specifically focused on compliance with CA pedigree
  - Ongoing evaluation of solution vendor proposals
  - Upgrading ePedigree capabilities to accommodate serialization
  - Planning Pilots with trading partners in each segment:
    - Wholesaler
    - Chain Drug Store
    - Third Party Manufacturer
    - Private Labeler
    - Re-Packager

Implementation Timeline

- TEVA is currently formulating an implementation timeline
- Factors impacting timeline:
  - Multiple, different customer requirements
  - Equipment availability
  - Equipment validation
  - Potential labeling changes
  - Outsourced suppliers' ability to implement

Estimated Implementation Costs

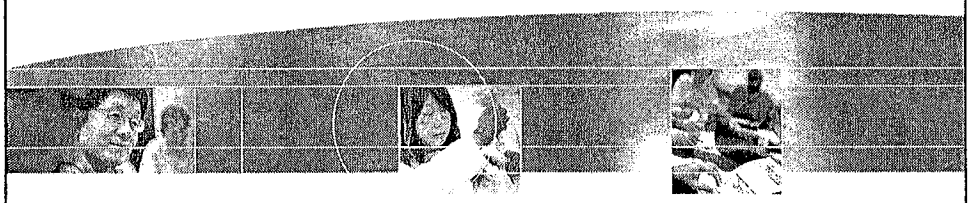
- $35 Million estimated cost to install equipment capable of serialization (2D) on packaging lines only; not including incremental labeling costs or costs associated with distribution centers
- Tens of millions of dollars in additional operating costs per year
- Each implementation is unique and complex:
  - Varying line speeds
  - Non-standardized equipment
  - Available footprint / line space

In Conclusion

- TEVA supports a multi-faceted, risk-based and phased-in approach involving business practices, legislation/regulation, enforcement and technology to address issues that impact patient safety

- TEVA requests that the Board postpone as soon as possible the implementation date of the California Pedigree Law to:
  - Ensure continued supply of the full breadth of generic pharmaceuticals to the citizens of California
  - Enable the pharmaceutical industry to take the time needed to adopt a practical system at a reasonable cost

Watson



California Board of Pharmacy Enforcement Committee Meeting

Mary Woods
Exec. Director Call Center Operations
December 5, 2007
E-Pedigree

Agenda

- Background-Corporate Profile
- E-Pedigree Actions to Date
- Challenges
- Impact
- Next Steps
- Summary

Watson 2

Commitment to Patient Safety

Watson's Vision is inspired by our commitment to improve the health and quality of people's lives worldwide, we are fully dedicated to being a leading provider of pharmaceutical products.

As a testament to that statement our allegiance is to continually improve our practices to ensure a safe and secure product supply chain. Patient safety programs are always at the forefront of our business.

Watson 3

Watson At A Glance: Corporate Profile

Watson is a leading specialty pharmaceutical company that generated $1.98 Billion in revenues in 2006 in three distinct business segments, Generics, Brand, and Distribution

Background	Product Lines	Locations
Established in 1984	Over 150 product families	13 Sites in US
3rd largest supplier of generic pharmaceutical products in the US.	Over 500 RX SKU's	Coleraine, Northern Ireland
**5th largest pharmaceutical company in US in total RX's dispensed.	Shipped 59MM RX selling units in 2006	Goa & Mumbai, India
	**229MM RX's Dispensed 2006	Shanghai & Changzhow, China

** Source IMS Data 2006

Watson 4

E-Pedigree Actions to Date

- Support of all customer requirements to meet prior states pedigree requirements.
- Vendor and E-Pedigree application selection
- Long term serialization strategy
- Actively involved in industry and regulator task force
- 2 year RFID pilot with a Watson customer
  - Modified 1 packaging line
  - UHF Gen1 & Gen2 RFID pre-serialized labels
  - Scanners, Readers, licenses
  - Significant commitment and investment to investigative technology

Watson 5

Challenges

- Standards still being developed
- Interoperable technology guidance between manufacturers and different COT's.
- Outsourced manufactured product considerations
- Timeline constraints for manufacturing equipment installation, testing, and validation

Watson 6

Impact

Manufacturing

- Product supply considerations during equipment installation and validation
  - 6 mfg. sites, 32 packaging lines, shipping areas
  - Site specific evaluation based on product packaging
  - 500+ sku's
  - Approx. 60MM units
  - 2 Distribution centers
  - Approx. capital expenses $15-20MM

Patient

- Cost impact to patient population

Watson 7

Next Steps

- E-Pedigree application implementation, trading partner testing, & deployment
- Long term serialization strategy prioritizing determined high risk products, and interoperable technology methods.
- Would consider on-going projects/pilots with selected wholesalers/distributors/chains to test interoperable technology
- Continue to participate as active members on industry councils and with regulators to solidify working standards for healthcare industry, and provide a safe and secure supply chain.

Watson 8

Summary

- Watson is committed to patient safety and enforcement of a safe and secure supply chain.
- Watson will continue to move forward in our efforts to meet California E-Pedigree requirements.
- Watson will continue to participate in efforts with selected customers for testing of interoperable solutions.
- Watson requests consideration for an extended implementation date by the CA BOP to ensure standards are in place, and to protect the integrity of the supply chain while continuing to provide lower cost alternative pharmaceutical products to Patients.

Watson 9

Statement PhRMA

December 5, 2007

Efforts Underway To Enhance Supply Chain Security— Electronic Pedigree Offers Near-Term Patient Safety Benefits

Overview

- PhRMA fully supports public policy objectives to further strengthen the U.S. pharmaceutical supply chain and to help ensure patient safety, which lies at the heart of PhRMA companies' discovery and manufacturing of medicines.
- Any legislative or regulatory requirements to authenticate products and pass pedigree information should be uniform, should apply to all parties in the pharmaceutical supply chain, and should recognize the recent federal requirement for a standardized numerical identifier. Supply chain security is the responsibility of all parties involved in the distribution of products to American patients.
- PhRMA believes there is no technological "silver bullet" to protect against counterfeits. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. They have also adopted a range of business processes to better secure the supply chain and help facilitate the early detection of criminal counterfeiting activity. These are additional tools in the "tool box" to help strengthen the security of the pharmaceutical supply chain.
- Electronic pedigree is a viable near-term solution to help enhance patient safety and to provide additional supply chain security, while the necessary development, testing, certification and implementation work is being completed to support risk-based serialization.
- PhRMA supports mandatory use of electronic pedigree by all parties in the pharmaceutical supply chain, initiated by the manufacturer at the first commercial sale.
- PhRMA supports item-level serialization of products at high risk for counterfeiting, using a phased approach.
- PhRMA supports strong penalties for counterfeiters, including increased criminal penalties of 20 years' imprisonment, to help deter counterfeit activity.

Electronic Pedigree Should be Required for All Products as a Near-Term Solution

- Electronic pedigrees, available now, combined with lot-level information identification, provide a near-term solution to further secure the pharmaceutical supply chain and help enhance patient safety. Manufacturer-initiated electronic pedigrees could be implemented for all products at the lot level by the end of 2009.
- Manufacturers already use lot-level tracking for a number of functions, including product recalls, to help ensure patient safety. Lot-level tracking is one component of the Food and Drug Administration's (FDA's) current Good Manufacturing Practice (cGMP) requirements. By making this information available to downstream trading partners via electronic pedigree, the benefits of lot-level serialization could be used throughout the pharmaceutical supply chain.

- The FDA's cGMPs also require reconciliation of products. Reconciling product by the number of units received of a given lot number against product sold would assist the ability of trading partners to detect counterfeit items.
- Electronic pedigree with lot-level serialization provides an additional measure of security to the prescription drug supply, and would work in tandem with other overt and covert anti-counterfeiting technologies already employed by manufacturers. The entire supply chain would be accountable for documenting the source and chain of ownership for all products distributed. This would help close gaps that counterfeiters try to exploit to introduce counterfeit products into the legitimate supply chain. In addition, electronic pedigree, without serialization, has and will continue to help facilitate investigation and prosecution of counterfeit cases, and thus may have a deterrent effect.
- The FDA supports the use of electronic pedigree, and thus, PhRMA's position is aligned with the Agency's.
- The use of electronic pedigree at the lot level complies with the statement of intent of the California legislature in section 4163.1 that: "manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationship in the distribution of dangerous drugs with wholesalers," pending technological feasibility of serialization.

Many Steps are Required Before Item-Level Serialization Can Begin; Technology Limitations and Other Challenges Directly Affect the Pace of Implementation

- While lot level serialization exists today – as required by FDA's cGMPs – the extension of this serialization effort to the case, or even the unit level, requires a myriad of activities by all supply chain partners. This collaborative effort to determine a viable technology standard has been adopted as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), and should be followed by future state legislative requirements.
- The implementation of unique identification beyond lot level will require significant changes to current manufacturing processes and facilities, many of which will require the development of guidance and/or pre-approval from FDA. Changes to manufacturers' labels and packaging may also require prior FDA approval.
- Significant data ownership and access issues must be resolved prior to item-level serialization, including relating to data exchange between supply chain partners, processes for verification of serial numbers, and issues related to commissioning and decommissioning a serial number.
- Processes to ensure the integrity of any track and trace technology will also be necessary.
- All of these activities – as well as the development and ratification of open standards which is described in more detail below -- must occur before any broad implementation may begin. The multiple steps required to implement serialization for all products or even a subset of products cannot realistically be completed by January 2009.
- The deployment of interoperable systems across the entire supply chain is a required prerequisite to implementation of the California pedigree law and is necessary to support the passing of pedigree and serialization information. The industry as a whole has significant work yet to complete before interoperability is possible.
- The implementation of electronic pedigree should not be delayed until these challenges have been resolved.

The Development of Open Standards is Necessary Before Item-Level Serialization Can Begin

- Serialization requires that open standards be developed and adopted in a number of areas, in addition to the activities described above.
- Specific standards that must be developed, include, but may not be limited to: RFID high-frequency item level serialization, serial number format for RFID, discovery configuration and installation, and discovery services. These standards must also address complex issues surrounding data integrity, interoperability, and compatibility across the supply chain.
- The standards described above have not been developed and/or ratified, and will not likely be available until mid-2008 -- at the very earliest -- and possibly as late as 2009.
- Once these standards are finalized, vendors marketing technology solutions will need to be certified to those standards and products built to conform to these standards. These steps must be completed before item-level serialization can begin, beyond planned pilot activities.

Recent Federal Legislation Directs FDA to Develop a Standardized Numerical Identifier by 2010; Any State Requirements Should Not Take Effect Until This Federal Process is Completed

- The recently-enacted FDA Amendments Act of 2007 (FDAAA) directs FDA to develop – no later than March 27, 2010 -- a standardized numerical identifier to be applied "at the package or pallet level" to prescription drug products. In developing this identifier, FDA must consult with supply chain stakeholders and other relevant federal agencies and consider a variety of technological options.
- The terms "package" or "pallet" are undefined in the legislation, and thus, may not necessarily be read as automatically requiring that the standardized numerical identifier be applied to individual units of certain prescription drug products.
- The FDA is still considering the scope of its mandate under these provisions and developing a process to gain input from stakeholders and implement these requirements.
- The proliferation of differing state and federal requirements in this area would create confusion and could potentially negatively impact the pharmaceutical supply chain; therefore, one uniform, national standard is necessary.
- We recommend that California work with FDA as it develops a standardized numerical identifier, and consider delaying implementation of its state requirements to ensure that conflicting requirements do not result.

Product Level Serialization Should be Phased-in for Certain "High Risk" Products; Risk-Based Approach Will Facilitate Supply Chain Security

- A viable solution would be to begin with electronic pedigree at the lot level for <u>all</u> products and then phased in serialization at the case or item level for products most at risk for counterfeiting or diversion. Time and resources should be focused on those products whose counterfeiting would present the greatest safety risks to patients, such as life-saving medicines, or medicines most attractive to counterfeiters.
- The use of electronic pedigree at the lot level ensures that all drug products undergo security screening throughout the distribution channel, and phasing in serialization at the item level for those products identified at high-risk adds an additional layer of security.

- Any risk-based serialization approach should allow for the use of flexible technologies (e.g., 2D bar code or RFID) because certain medicines may not be amenable to particular technologies for package serialization, such as biologics.
- The FDA has recognized the value of a risk-based approach that focuses manufacturers and downstream partners on medicines at greatest risk of being counterfeited. Criteria has been developed by FDA to assist companies in identifying prescription drugs at high risk of being counterfeited, in order to support this risk based, phased-in approach to serialization.

Conclusion

- PhRMA fully supports public policy objectives to further strengthen the U.S. pharmaceutical supply chain and to help ensure patient safety.
- PhRMA supports one uniform standard for the authentication of products and the passing of pedigree information.
- PhRMA supports the use of electronic pedigree without serialization as a viable near-term solution to help enhance patient safety and to provide additional supply chain security. PhRMA supports the mandatory use of electronic pedigree by all parties in the pharmaceutical supply chain.
- PhRMA supports item-level serialization of certain products at high risk for counterfeiting, using a phased approach.
- PhRMA supports the use of interoperable systems throughout the supply chain to support the passing of pedigree and any serialization information.
- PhRMA looks forward to continuing to work with the California Board of Pharmacy and other supply chain stakeholders but is concerned that all steps required to achieve interoperability may not be reached by January 2009.

Member Survey Results

California Board of Pharmacy
December 5, 2007

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California Healthcare Institute

- CHI is a statewide organization representing the state's life sciences industry.
- More than 250 of the state's premier life sciences companies—biotechnology, medical device, diagnostics and pharmaceutical companies, as well as the state's leading universities and private research institutions.
- Mission – To advocate for policies that promote medical innovation, access to the best medicines and therapies, and the health and well being of patients.

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Membership

- Member Organizations
  - 40% biotechnology
  - 26% service providers
  - 14% medical device/diagnostics
  - 13% pharmaceutical
  - 6% Academic and Private Research Institutions
- Innovators
  - 42% have one or more products on the market
  - 46% of those with products have revenues of less than $100 million and fewer than 500 employees
  - Products range from inhaled and infused biologics, injectables, vaccines, implantable medical devices, diagnostic equipment and traditional chemical pills

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Survey Outline

- Conducted a survey of our members in conjunction with the Biotechnology Industry Organization (BIO).
- Purpose – To get a picture of what our members are doing to implement the e-pedigree law and an understanding of the challenges and issues they face in doing so.

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Respondent Profiles

- **Products on the market**
  - 17% more than 25; 33% between 10-25; 11% between five-10; 39% fewer than five
- **Manufacturing facilities**
  - 5% more than seven; 47% between four and seven; 32 % between one and three; and 16% do not manufacture their own products
- **Packaging lines**
  - 5% have more than 20; 42% between 10-20; 37% between one-10; 16% have no packaging lines
- **Distribution centers**
  - 5% have four; 16% have three; 42% have two; 32% have one; and 5% have no distribution centers
- **Third party partners/contract manufacturers/other logistics providers**
  - 16% more than six; 56% between 4-6; 28% between one and three

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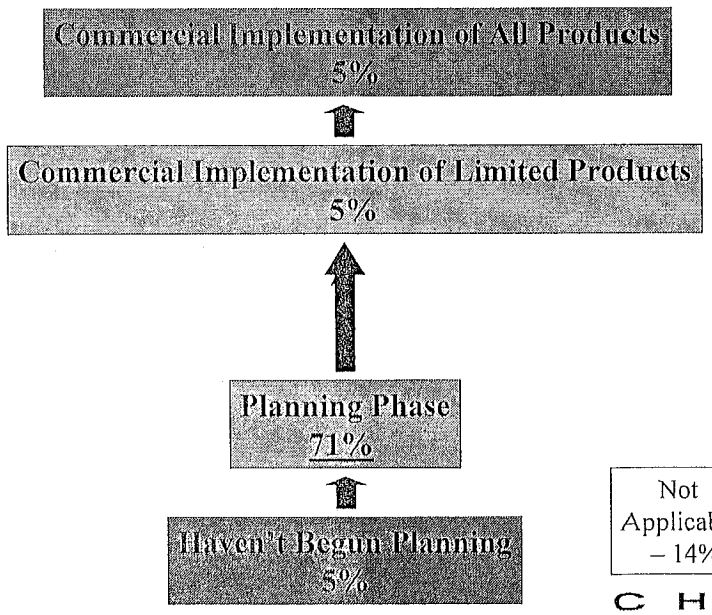
Serialization Implementation Status



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Planning Phase

- Testing various technology applications internally
- Pilots with other members of the supply chain
  - 36% expect to pilot in 3-6 months
  - 29% expect to pilot in 6-12 months
  - 29% expect to pilot in 1-2 years
  - 7% expect to pilot in 2+ years

Challenges

- Technology concerns
- Production concerns
- Third party concerns
- Cost concerns

Technology Issues

- Adopting an appropriate technology platform
  - No consensus among supply chain members (RFID vs. 2-D barcode)
  - Significant timing issues to meet implementation date
  - Infrastructure issues--data storage and ownership issues
- RFID
  - Use has not been validated with biologic products
  - Read-rates with downstream partners.
- 2-D Barcode
  - Throughput issues for receiving
  - Read-rates with downstream partners.

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Production Issues

- Lack of surplus packaging capacity required to ensure a continuous supply of product while the packaging lines are being reconfigured for unit level serialization.
- Good Manufacturing Practices (GMP)—Consequences if FDA approval is required for changes to packaging lines.
- Developing and implementing a serialization system is complex and expensive, requiring the installation and validation of new software and equipment.
- Accelerated stability testing will be required to ensure that the application of RFID tags to individual units does not affect a biologic medicine's integrity, physical characteristics or efficacy.

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Third Party Business Partner Issues

- Majority of our members rely on third party manufacturers, packagers, labelers and carton suppliers to get their products into distribution.
- Concern about our business partners' ability to comply.
- Even if our business partners can become compliant, our smaller members are extremely concerned about their needs being met.

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Third Party Solution Provider Issues

- Uncertain if technology providers have technology in place that is reliable and interoperable throughout the supply chain.
- Even if there are viable technology solutions, our smaller members are extremely concerned about their needs being met.

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Cost Issues

- More of an issue for smaller companies.
- Product serialization at each step of the drug distribution chain will require significant upfront and ongoing costs.
- Must dedicate significant human resources to compliance, a not insubstantial burden for many of our smaller companies.
- Must be sensitive to the ultimate concern about adding costs to the healthcare system as a whole.

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Summary

- 10% of our respondents believe they can be prepared to implement serialization across all or some of their product lines.
- The vast majority are in the planning phase.
- Our members support the law's goal of product integrity and patient safety.

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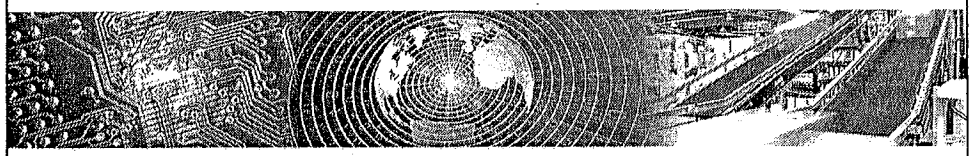


EPCglobal Update

State of Pedigree and EPC/RFID Standards

California Board of Pharmacy

December 5, 2007

Mike Rose, Tri-Chair, EPCglobal HLS IAG
Ron Bone, Tri-Chair, EPCglobal HLS IAG

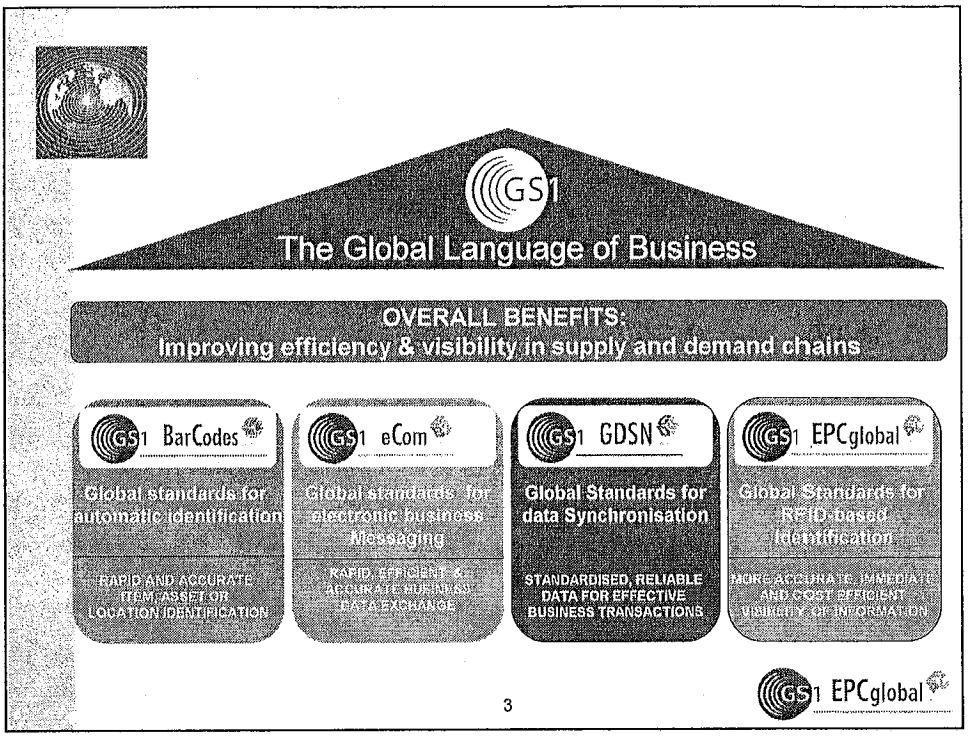
Bob Celeste, EPCglobal North America

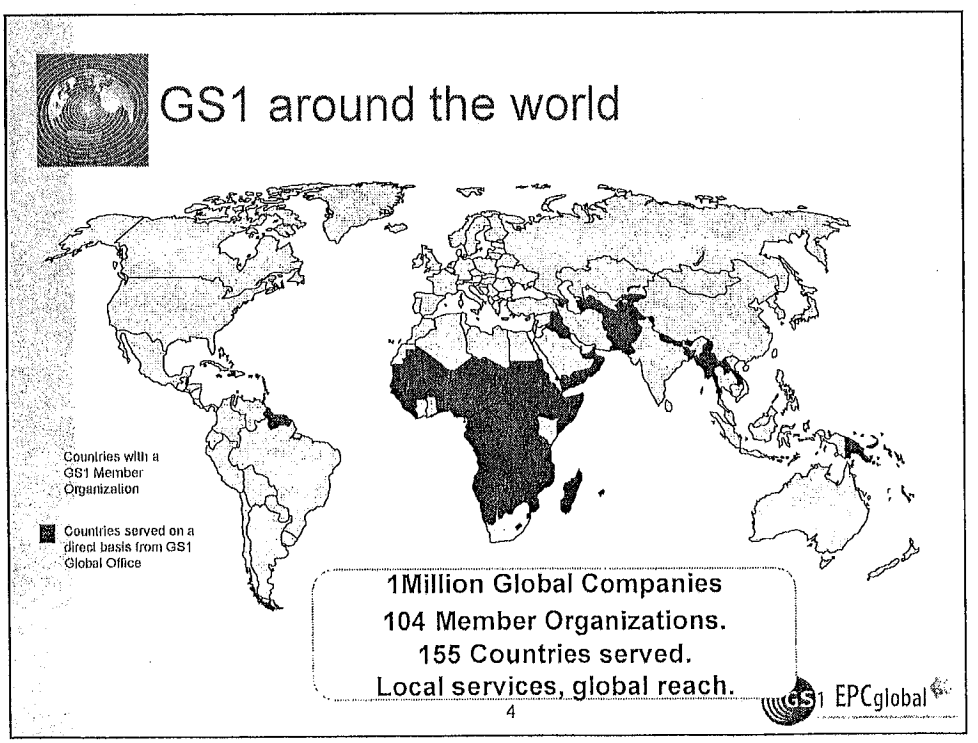
GS1 EPCglobal

Overview

- State of the Standards
- Focus on Pedigree/EPCIS Assessment

GS1 EPCglobal


GS1
The Global Language of Business
OVERALL BENEFITS:
Improving efficiency & visibility in supply and demand chains
GS1 BarCodes
Global standards for automatic identification
RAPID AND ACCURATE ITEM, ASSET OR LOCATION IDENTIFICATION
GS1 eCom
Global standards for electronic business Messaging
RAPID, EFFICIENT & ACCURATE MULTI-INDUSTRY DATA EXCHANGE
GS1 GDSN
Global Standards for data Synchronisation
STANDARDISED, RELIABLE DATA FOR EFFECTIVE BUSINESS TRANSACTIONS
GS1 EPCglobal
Global Standards for RFID-based Identification
MORE ACCURATE, IMMEDIATE AND COST EFFICIENT VISIBILITY OF INFORMATION
3
GS1 EPCglobal


GS1 around the world
Countries with a GS1 Member Organization
Countries served on a direct basis from GS1 Global Office
1Million Global Companies
104 Member Organizations.
155 Countries served.
Local services, global reach.
4
GS1 EPCglobal

About GS1 US

- Formerly known as the UCC
  - Established 1973 (think U.P.C.)
- Implements the GS1 System in the U.S.
  - 23 industries, 280,000 members in U.S.
  - 18,000 identified healthcare members in U.S.
  - Uniquely identify products, assets and locations
  - Bar codes, EPC, e-Commerce, UNSPSC®
- Voluntary, not-for-profit, member driven

GS1 EPCglobal

GS1 Healthcare US – Relation to GS1 Healthcare

- **GS1 Healthcare Role:**
  - Global focused
  - The Standards Development per Roadmap
  - Ensuring global standards harmonization
  - Communication on global standards and activities
- **GS1 Healthcare US Role:**
  - US focused
  - Primary customer contact for US based companies / divisions and regulators
  - Drive adoption / implementation
  - Non-voting comment to global standards development

GS1 EPCglobal

Drive adoption / implementation?

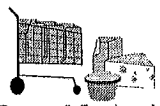
- Pilots
- Business cases
- Education
- Solution provider outreach – identify product needs, minimum software support abilities, etc.
- Scorecards
- Advise US regulators
- Coordinate with existing industry groups
- Implementation guidelines
- Drive R&D

GS1 EPCglobal

User Overview - 23 Sectors

Public Sector
- Defense and Homeland Security

Healthcare and Pharmaceuticals
- Over-The-Counter
- Pharmaceuticals
- Medical/Surgical



Grocery & Foodservice
- Food and Beverage, including Foodservice
- Alcohol Beverage

Other
- Service Industry (Market Research)
- Utilities (Power Transmission)

Publishing
- Books, magazines, maps, calendars, greeting cards

Durable Products
- Automotive
- Building Materials (Building Supplies/Home Improvement)
- Information Technology/ Computers (Computer Hardware/ Software/ Electronics)
- Photographic Equipment/Cameras/Binoculars/ Telescopes

Industrial/Commercial
- Agriculture (Agricultural/Farming, Tobacco)
- Chemicals (Household and Industrial Chemicals)
- Maintenance-Repair-and-Operation, Raw Materials, Packaging

Retail - General Merchandise, Apparel, and Specialty
- Apparel and Fashion Accessories
- Audio/Video
- Furniture (indoor)
- Hardline Merchandise/Home Accessories (Home Accessories, General Merchandise, Toys & Games, Baby Products, House wares, Office/School Supplies, Hobbies, Domestics/Linens, Seasonal Products)
- Cosmetics and Fragrances
- Leisure Industries (Outdoor Furniture/BBQ Grills & Accessories/Wood/Ice Chests/Environmental, Sports Equipment/Physical Equipment, Lawn & Garden, Marine Accessories)
- Music Products - Instruments and Sheet Music

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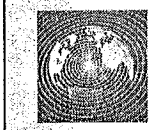

Early Market Adopters

Retail	Consumer Goods	Food & Beverage	Healthcare & Life Sciences	Electronics & High Tech	Logistics & Transport
WAL*MART	P&G Gillette	General Mills	Johnson & Johnson	Gateway	FedEx
CVS	Kimberly-Clark	Kellogg's	Abbott Laboratories	IBM	UPS
Albertsons	Sara Lee	Coca-Cola	Pfizer	hp invent	United States Postal Service
Target	The Maytag Corp.	Dole	Baxter	Motorola	DHL
Best Buy	Elizabeth Arden	Del Monte Foods	Wyeth	Microsoft	Maersk Line

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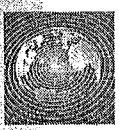

Emerging New Industries

Aerospace & Defense	Chemical	Industrial	Footwear & Apparel	Automotive
Boeing	Dow	3M	Perry Ellis	Goodyear
Lockheed Martin	Rohm and Haas	Komatsu	Jockey	Michelin
Honeywell	ExxonMobil	Porter Cable	Levi Strauss & Co	Johnson Controls
GE	DuPont	Weyerhaeuser	Russell	John Deere
Pratt & Whitney	Chevron	Black & Decker	VF Corporation	

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Healthcare – who we are working with …

- **Industry**
  - Pharmaceutical Manufacturers
  - Medical Device Manufacturers
  - Distributors
  - Retail Pharmacies
  - Hospitals
  - GPOs
- **Regulatory**
  - FDA (Pharma, Med Devices)
  - State Boards of Pharmacy
  - DEA, EPA, FCC
- **Associations**
  - AHA
  - BIO
  - CSHP
  - HDMA
  - HIMSS
  - NACDS
  - PhRMA
- **Universities**
  - MIT – Auto-ID Labs
  - Drexel University
  - Stanford University
  - University of Wisconsin
  - University of Einhoven
  - University of Arkansas

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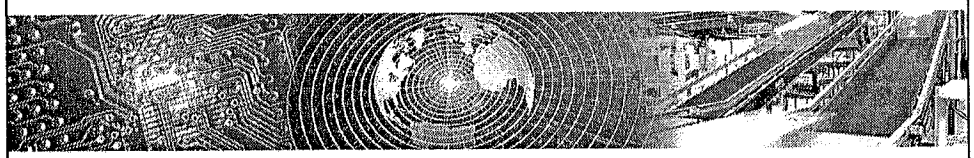

Standards Development

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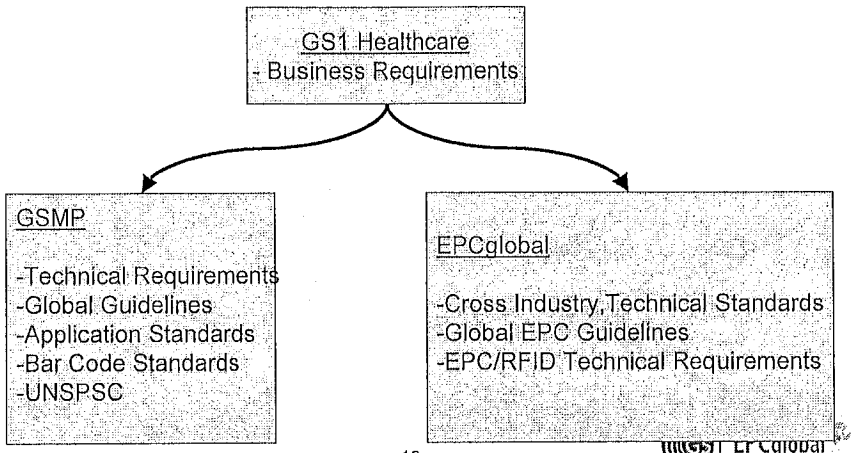
Standards Development Flow

For Healthcare related Standards



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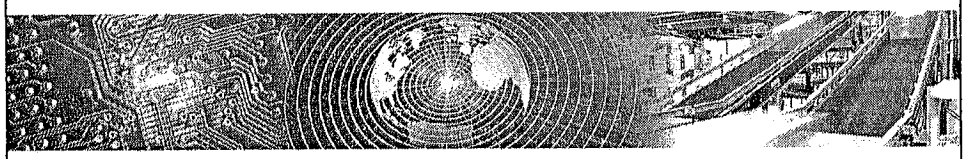
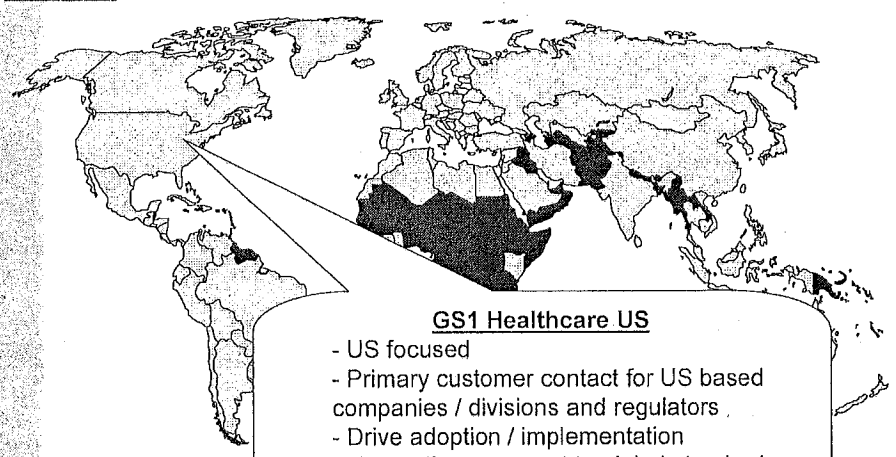


Standards Adoption

GS1 Healthcare US...



GS1 Healthcare US

- US focused
- Primary customer contact for US based companies / divisions and regulators
- Drive adoption / implementation
- Non-voting comment to global standards development

GS1 EPCglobal

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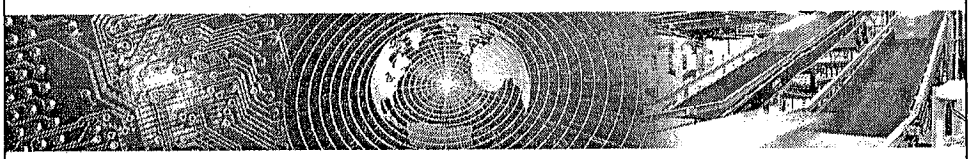
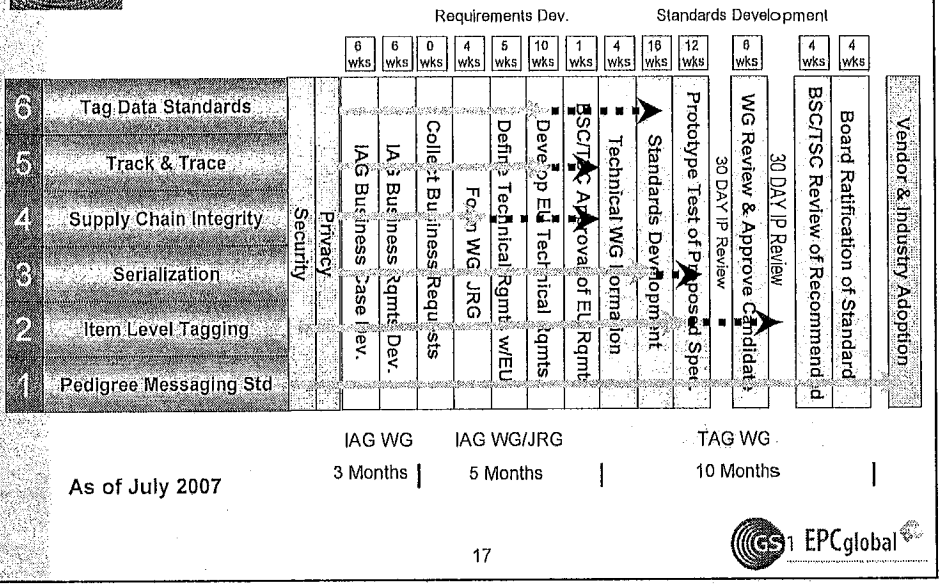


EPCglobal Healthcare Standards

GS1 EPCglobal

Standards Update



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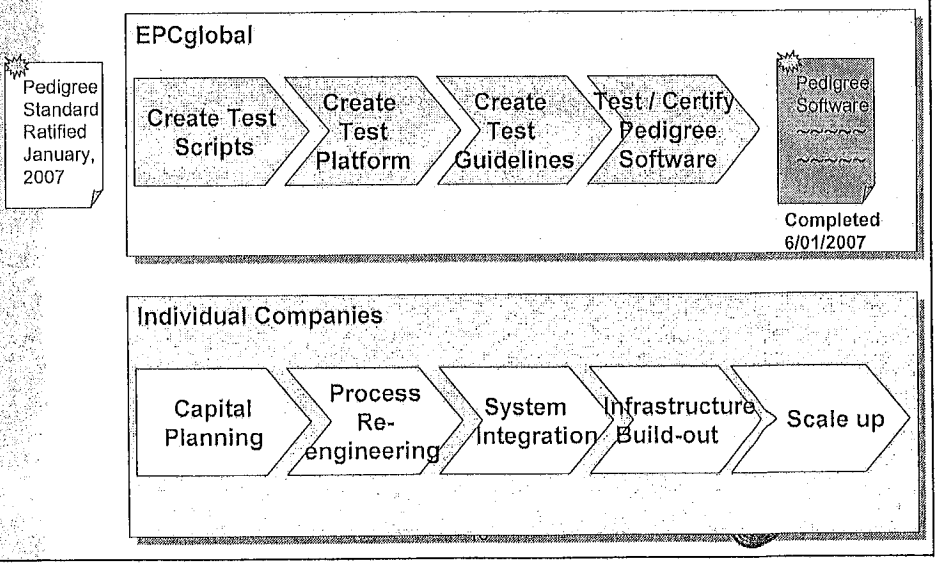
Post Ratification Activities

Example: Pedigree Messaging Standard



Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- **Ratified standard – 01/2007**
- Certification Program - 3 companies certified
  - ✓Axway
  - ✓rfxcel
  - ✓SupplyScape
- Education and awareness web seminars

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '08.
- Completed vote for item level tagging requirements document
- Ratification of standard anticipated 1Q/07
- Anticipate silicon available for prototyping 2Q08

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Pharma Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
  - Joint HUG/HLS Work Team
- Medical Devices, Biologics & other Business Requirements started

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Predominately HLS, however, cross industry work group expected
- Authentication and decommission alternative scenarios identified
- Anticipate completion by end of October

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Integrate with GS1 Traceability efforts
- Track & Trace to be interoperable with Pedigree Model
- Additional use cases addressed:
  - Repackers
  - To be done: 3rd Party Logistics Providers & Product Recall
- Sub-team within Supply Chain Integrity focused on security and pedigree integration
- Data Sharing Strategy & Guidelines will addressed in Data Exchange JRG
- Common vocabularies and location identifiers incorporated into just ratified EPCIS Standard

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Standards Update

6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Tag Data JRG focused on defining additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status:

- Work underway. Defining common data structure that can be used by all industries.
- Captured business requirements
- Comment phase approved
- Specification phase started

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Industry Adoption Task Force
Executive Summary

- Mission:
  - Define a 'starting set' of guidance for industry trade associations
  - Work closely with EPCglobal and GS1.
  - Educate and hand-off the Roadmap to industry trade associations.
- Objectives:
  - Guidance on: Unique Identification based on Serialization.
  - Guidance on: Carrier and Auto-Identification Alternatives
  - Guidance on: Providing Pedigree information:
  - Guidance on: Trading Partner Action Steps for Adoption
- Timeline:
  - Document presented to numerous groups
  - Comments resolved
  - Document to be published December 2007

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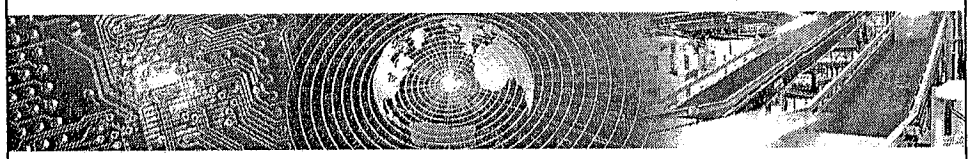

EPCglobal HLS Update
Follow up Items

Follow Up Items
From
March 8, 2007 Pedigree Workshop
with
Subset of California Board of Pharmacy

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Follow Up Items Summary Update

Current Status

Weekly conference calls to work on follow up items

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Assign Responsibility	Document & Identify Item	Status
Individual company	Business Practice	On going
Pedigree WG	Supported by Current Standard	Completed
Pedigree WG	Supported by Current Standard	Completed
Industry Assoc	Supported by Current Standard	Completed
Pedigree WG	Supported by Current Standard	Completed
Individual company	Business Practice	Completed
Industry Pedigree WG	Standard enhancement	Completed
Individual company	Supported by Current Standard	Completed

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1. Unit Dose Serialization Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgrs sellable unit may be "broken down" and sold as eaches.

Issues:

1. How are the eaches serialized
2. What is the impact to Repackers
3. How will Repackers continue the pedigree

Assignment: Individual Company

Status:

- Business process issue for Supply Chain stakeholders to address level of serialization

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2. Receipt of Partial Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Orders are not always received complete, having likely pedigree implications.

Issues:

1. How often does this occur
2. What pedigree or business process changes may be required

Assignment: Pedigree Workgroup

Status:

- Current Pedigree standard addresses partials receipts

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3. Drop Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgrs ship certain products to end-customers, while billing goes through wholesalers.

Issues:

1. Where should the pedigree be sent
2. What transaction information should it reflect

Assignment: Pedigree Workgroup

Status:

- Current Pedigree std addresses drop shipments

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4. Sign & Certify Inbound Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Signature and certification of in-bound shipments, as well as out-bound.

Issues:

1. Evaluate the implications of not using inference

Assignment: Industry Associations

Status:

- Standard supports signing requirements for in-bound and out-bound

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5. Resale of Returned Product Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: There are times when saleable product is returned by the Whlsr to the Mfgr and may be resold by the Mfgr.

Issues:

1. Customers may not want returned product if the pedigree must reflect the previous distribution of the product.
2. How should a pedigree treat this transaction – reflect all previous movement of the product, or start anew when sold by the Mfgr
3. What documents, processes, controls and enforcement would be required

Assignment: Pedigree WG

Status:

- Pedigree standard addresses Resale of Returns

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6. Intra-Company Transfers Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree Status for intra-company transfers into CA.

Issues:

1. Product sold to a Whlsr to an out-of-state location that does not require a Mfgr originated pedigree may be intra-company transferred to CA.
2. What are the CA pedigree implications

Assignment: Individual Company

Status:

- Standard supports manufacturer and/or wholesaler originated pedigrees

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7. Voided Pedigrees Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree needs to be updated or changed to correct simple administrative errors such as shipping wrong product or incorrect serial number.

Issues:

1. What is the process of voiding pedigrees where an error has occurred, or a product has been returned
2. How are pedigrees for products marked for destruction managed

Assignment: Industry & Pedigree WG

Status:

- Identified as a pedigree management issue
- Initiating Work Group to address issue; in the interim, Standard provides guidelines & best practices

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8. Inference Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Whether inference will be allowed at any step requiring "certification of the receipt", meaning that the receipt is positively affirming that they received all of the products specified in the pedigree without physically verifying all serial numbers.

Issues:

1. Does the pedigree std allow two separate signature events for one receipt step (one to receive, one to certify at a later date),
2. What is the Industry's view on inference and it's application
3. Is there a time limit from inbound receipt inference until all unique ID numbers have been certified

Assignment: Industry Adoption Workgroup

Status:

- Establishing a set of inference recommendations

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Next Step

- In process of scheduling another pedigree workshop with the following recommended objectives:
  1. Review status of the work on the follow up items in detail,
  2. Discuss impact to standards, and
  3. Review work of the Industry Adoption workgroup

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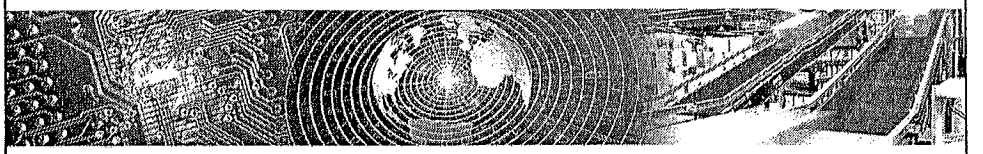

Electronic Tagging and Marking Options

GS1 EPCglobal

Barcodes and RFID

Marking and Tagging Pharmaceuticals

Individual Items

National Drug Code (NDC)

Unique identifier
For pharmaceuticals
Within the US
Managed by FDA

Global Trade Item Number (GTIN)

Unique identifier
For pharmaceuticals
Globally
Managed by GS1

Barcode Symbology

RFID Tag Encoding

Shipping Units

Serialized Shipping Container Number (SSCC)

Unique identifier
For logistics units
(pallets, totes and shipping cases)
Globally Managed by GS1

Barcode Symbology

RFID Tag Encoding

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Barcodes and RFID

Differences and similarities

- Overlapping uses
- Different development trajectories
- Distinct reasons for choice
  - Thompson Memorial Hospital example

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Barcodes and RFID

Differences in Barcode types

- Linear Barcodes:
  - Commonly seen in retail and in logistics
  - Usually read by laser scanners – can be read by optical scanners
  - Size increments as additional data is stored
  - Large installed base

- 2D Barcodes:
  - Used in Pharmaceuticals, documents, retail
  - Read by optical scanners
  - Small size
  - Redundant data for fault tolerance

- Mixed types:
  - Used in retail for loose items (fruit)
  - Portions can be read by laser scanner. Serialized portion can be read by optical scanner
  - Relatively small size

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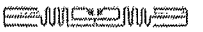
Barcodes and RFID

Differences in RFID types (passive)

- Ultra High Frequency:
  - Can be read from 0 – 5 meters
  - Fastest read speed
  - Reading around liquids and metals is a challenge (but not impossible)
  - Used in Pharmaceuticals, surgical sponges, etc.



- High Frequency (HF):
  - Used in Pharmaceuticals, books, access control
  - Moderate read speed
  - Usually larger than UHF

- Low Frequency (LF):
  - Used in manufacturing processes, access control
  - Slowest read speed
  - Very simple antenna design

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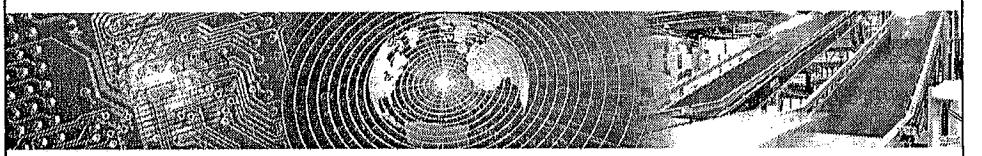

"The nice thing about standards is that there are so many to choose from."

... Thomas Rittenhouse, former CEO of the Uniform Code Council (GS1)

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Bar codes that do not support serialization

Carrier	Example	Data	Use Case	Other
UPC-A		GTIN-12	•Retail Point-of-sale	•Linear scanner
UPC-E		GTIN-12	•Retail Point-of-sale	•Linear scanner
EAN-13		GTIN-13	•Retail Point-of-sale	•Linear scanner
EAN-8		GTIN-8	•Retail Point-of-sale	•Linear scanner

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Bar codes that do not support serialization

Carrier	Example	Data	Use Case	Other
ITF-14 Type of Interleaved 2 of 5		GTIN-14	•Non-retail POS items (primarily preprinted corrugate boxes)	•Linear scanner

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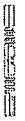
Bar codes that do support serialization

Carrier	Example	Data	Use Case	Other
GS1-128		•All GS1 identification numbers including application identifiers, as required •Max: 48 a/n characters •Serial Number 20 characters max	•Non-retail POS items •Logistics units (SSCC)	•Linear scanner
GS1 DataBar™ [Reduced Space Symbology (RSS)]		•All GS1 identification numbers including application identifiers, as required •Max: 74 a/n characters •Serial Number 20 characters max	•Loose produce •Variable measure items (meat/deli) •Coupons •Very small healthcare items	•Linear scanner
GS1 Data Matrix		•All GS1 identification numbers including application identifiers, as required •Max: 2335 a/n characters 3116 num characters •Serial Number 20 characters max	•Direct part marking •Very small healthcare items	•Image scanner required

GS1 EPCglobal

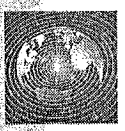
RFID tags that do support serialization

Carrier	Example	Data	Use Case	Other
EPC Gen 2 UHF passive Frequency 860-960 MHz		•All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag	•Item level •Logistics	•Range < 5m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPCglobal HF passive (under development) Frequency 13.56 MHz		•All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag	•Item Level	•Range < 2m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPC Active Tag (under development) Frequency 433 MHz		•All GS1 identification numbers including application identifiers, as required	•Logistics	

GS1 EPCglobal

GS1 Serialization Standards

- A serial number, identified with AI 21, is an alphanumeric field of up to 20 characters.
- The capacity of a 20 character serial number is huge.
  - The capacity of an all numeric serial number is 100 quintrillion ($100x\ 10^{18}$).
  - The capacity for an alphanumeric serial number is 13.36749 nonillion (13.36749×10^{30}) when just using 0 to 9 and A to Z.
  - If all 82 alphanumeric characters are used, the serial number has a capacity of 188.9196 undecillion (188.9196×10^{38}).
- The serial number must be unique in relation to the Global Trade Item Number® (GTIN®).
  - Example, serial number 1098765432AC may be associated with both GTIN 00614141123452 and GTIN 00614141999996.



GS1 Serialization Standards (2)

- The serial number is NOT to be parsed by trading partners.
  - There is no provision in the standard to support or enable this.
  - It is also contrary to basic GS1 principles that data elements are not to be parsed.
- Manufacturers may construct the serial number in anyway they see fit, including the use of internal logic or intelligence.
  - There exist no limitations or rules on serial number construction in GS1 standards.
- The SGTIN can always be represented as GTIN (AI 01) plus Serial Number (AI 21).
- The SGTIN-96 structure limits the serial number (AI 21) to a defined subset.
  - This subset is all numeric 38 bit field or 274,877,906,943 unique numbers.
  - This subset requirement exists due to chip size and cost considerations.

GS1 Serialization Standards (3)

- The SGTIN-198 structure completely supports the serial number (AI 21) - an alphanumeric field of up to 20 characters.

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Serialization Implementation Thoughts

- The GS1 community should build applications that support a serial number field of 20 characters.
- If a manufacturer has applied an Electronic Product Code™ (EPC) tag to a product and it is bar coded, then the information must match. Specifically, the GTIN must match and the serial number must match.
- Manufacturers that are unable to accept the serial number subset of the SGTIN-96 in an EPC tag will need to specify EPC tags that support SGTIN-198.
- The lot / batch number must be a distinct data element, defined as AI 10, both when bar coded and in an EPC tag, if it intended for trading partners to use. In a bar code it is AI 10 and in an EPC tag it would need to be in user memory. Should a manufacturer wish to include the lot / batch number in the construction of the serial number, this is their choice but the manufacturer can not expect any trading partners to parse out the lot / batch number from the serial number.

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Data Convergence

Bar Code and EPC - Different Data Formats

Different data formats for the same GS1 ID number

Data Output	00312345678906	0312345.067890.0 urn:epc.id:sgtin:0312345.067890.0
Data Capture		
GS1 ID Number Encoded in Data Carriers		

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URI Identification System

- URI are the addressing technology standards (IETF) for identifying resources on the Internet or private intranet. Fundamental component of World Wide Web.
  - Uniform Resource Locators (URLs) are addresses for network locations
    - Defines "where"
    - Example: www.gs1.org
  - Uniform Resource Names (URNs). A URN is a name that identifies an information resource on the Internet
    - Defines "what"
    - Example: urn:epc:id:sgtin:0029000.107313.2147488897
    - Foundation for "Internet of Things"

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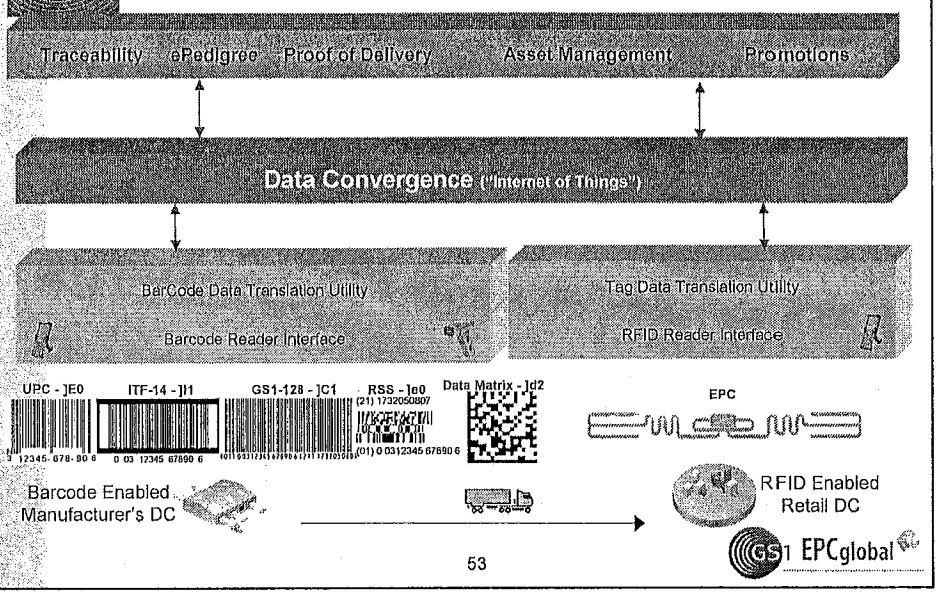
GS1 Barcode and EPC / RFID Convergence



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Adoption Activities Update

- GS1 Healthcare US
  - Product ID
  - Location ID
  - Global Data Synchronization (GDSN)
  - AutoID
    - RFID in Retail Pharmacy
  - Traceability Adoption
    - Pedigree/EPCIS Assessment

GS1 EPCglobal

Adoption Activities Update

Pedigree / EPCIS Assessment group (1/2)

- EPCglobal Pedigree Messaging standard is the only standard that meets FDA, State of Florida, State of Nevada and the State of California Pedigree regulations.
- In April, EPCglobal ratified the EPCIS standard.
- The EPCIS standard has been used to address a number of business issues (i.e. Proof of Delivery, Vendor managed Inventory, etc.) and improve sharing of product movement data within supply chains and company processes.
- A number of healthcare End User companies and Solution Provider Companies have approached EPCglobal concerning the possibility of using EPCIS in conjunction with the Pedigree Messaging standard to address Pedigree regulations.
-

GS1 EPCglobal

Adoption Activities Update

Pedigree / EPCIS Assessment group (1/2)

- We have research some material on the subject and have concluded that there may be possibilities in this type of approach.
- GS1 US and EPCglobal North America, through our GS1 Healthcare US initiative, will form a task force to assess the applicability of EPCIS within a Pedigree environment, determine compatibility with the current Drug Pedigree Messaging Standard and decide whether a US guideline or global standard would best fit the needs of the community.
- Once a conclusion is reached, GS1 Healthcare US will either continue the work towards the creation of a US guideline or present the findings to GS1 Healthcare (the global standards requirements body of GS1) for standards development.
- GS1 Healthcare US will hold a preliminary call on the subject of a "Pedigree / EPCIS Assessment Task Force" on December 13, 2007 at 2:00pm EDT. Details of this call will be available shortly.

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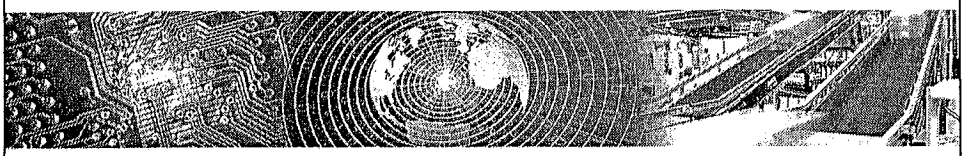
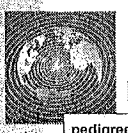


Pedigree Messaging Standard

GS1 EPCglobal



Pedigree / EPCIS Assessment - Background

Pedigree Messaging Standard sample

```
pedigree
  receivedPedigree Id="ReceivedPed-1"
    documentInfo
      serialNumber
      version
    pedigree
      shippedPedigree Id="ShippedPed-1"
        documentInfo
          serialNumber
          version
        initialPedigree
          serialNumber
          productInfo
          itemInfo
        itemInfo
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
          ...
        signatureInfo
      Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
    signatureInfo
  Signature (Wholesaler Signs: ReceivedPed-1)
```

Pedigree initiated by Manufacturer and received by Wholesaler

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Pedigree / EPCIS Assessment - Background

Pedigree Messaging Standard – core elements

- Document Info
  - Pedigree identifier
- Product Info
  - e.g. Product name, dosage form, etc.
- Item Info
  - e.g. Lot number, expiration date, serial number
- Transaction Info & Receiving Info
- Signature

- Shipped Pedigree
- Received Pedigree
- Initial Pedigree
- Repackaged Pedigree

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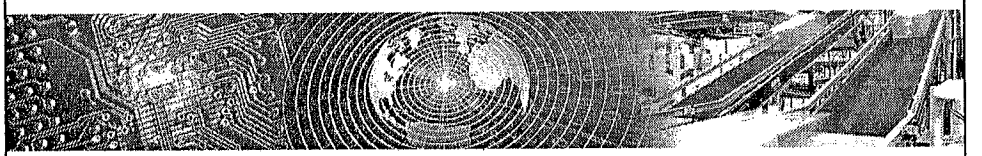


EPCIS Standard

GS1 EPCglobal

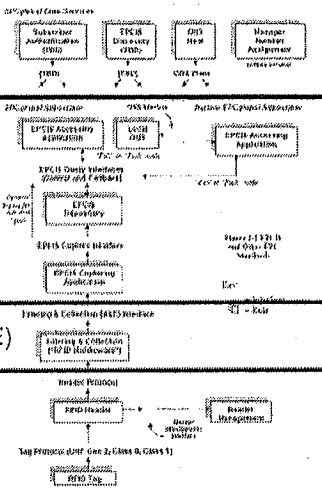
Pedigree / EPCIS Assessment - Background
EPCIS - EPCglobal Network standards

200? – Discovery Services & Subscriber Authentication

2006-07 – Electronic Product Code Information Service (EPCIS)

2005-06 – Filtering & Collection (ALE)

2005-06 - Tags & Readers



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Pedigree / EPCIS Assessment - Background
EPCIS

- Cross-Industry Standard
- EPCIS events answer 5 questions ...
  - Who
  - What
  - Where
  - When
  - Why
- EPCIS allows trading partners to "ask" for certain data about product disposition
  - Subscribe
  - Ad Hoc query
- Used by companies to ask internal questions and externally to communicate with Trading Partners
- *In the near future, you may use EPCIS in the form of ...*
  - Supply Chain
  - Hospital and Pharmacy applications

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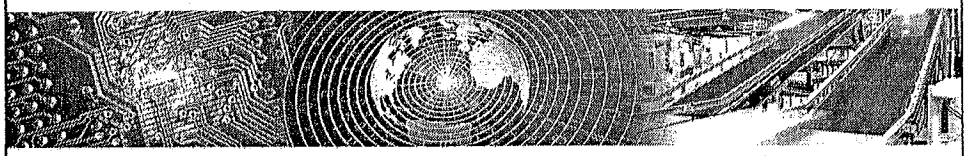
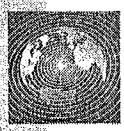
GS1 EPCglobal



Pedigree & EPCIS

GS1 EPCglobal



Pedigree / EPCIS Assessment

Pedigree and EPCIS

Pedigree Messaging Standard	EPCIS
• Document	• Who
• Product	• What
• Item	• Where
• Transaction	• When
• Receiving	• Why
• Signature	

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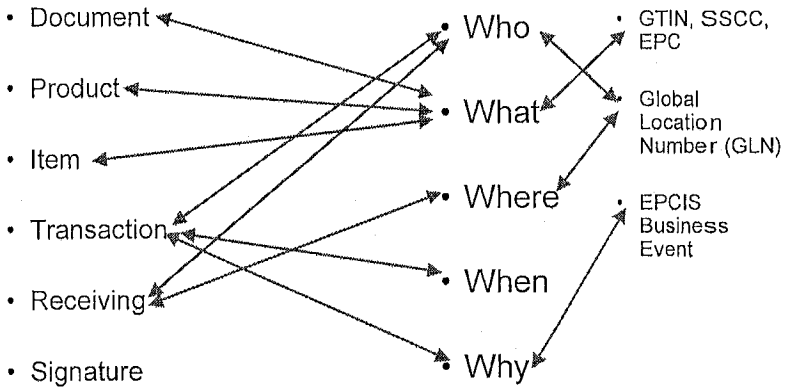
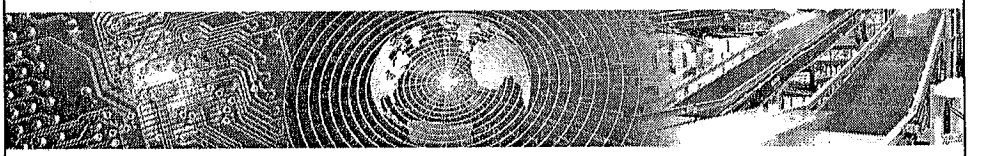
GS1 EPCglobal

Pedigree / EPCIS Assessment
Pedigree, EPCIS and GS1 Identifiers



GS1 EPCglobal

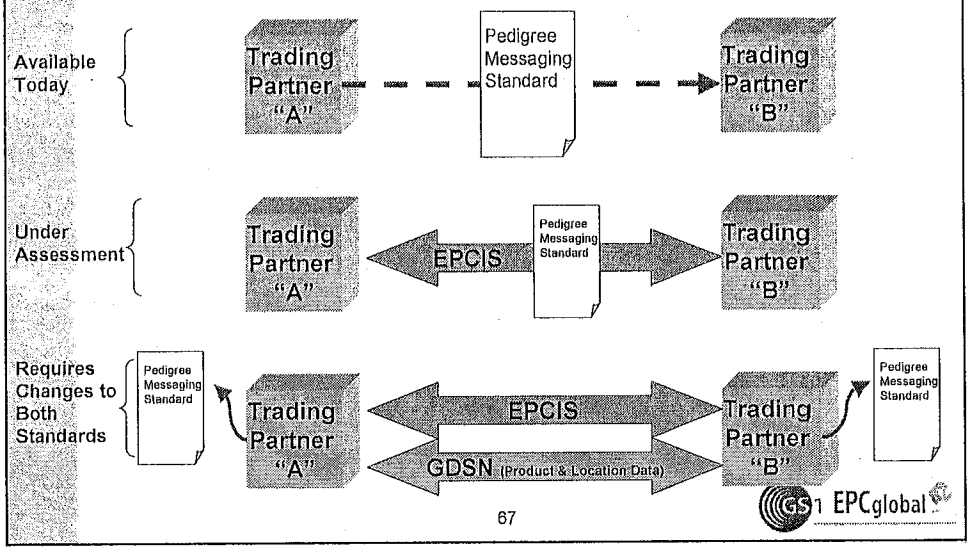


GS1 Healthcare US Pedigree / EPCIS Assessment group

Possible Outcomes

GS1 EPCglobal

Pedigree / EPCIS Assessment Group
Architectural proposals received



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GS1 EPCglobal

Pedigree / EPCIS Assessment Group
Possible recommendations

- US Guideline on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations
- Global Guideline on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations
- Global Standard on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations

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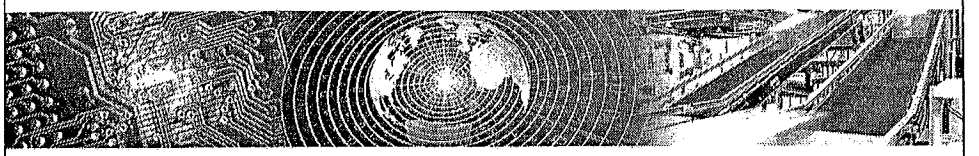
GS1 EPCglobal



Questions?

GS1 EPCglobal

- Draft -

Aegate: increasing confidence in patient safety

California Board of Pharmacy
December 5th 2007

aegate

Public

Secure Brands, Secure Business, Secure Patients

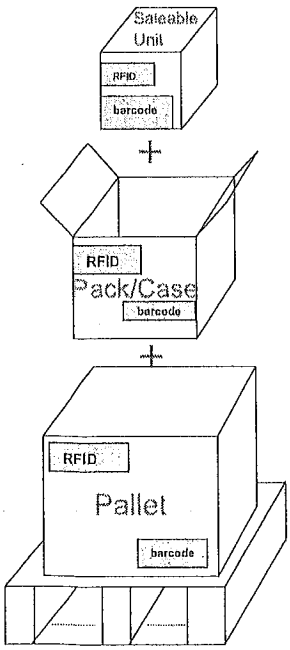
Contents

- Patient Safety
- Current e.pedigree legislation
- How can Authentication help?
- Aegate: Authentication progress across Europe
- **Proposed Californian approach**
- Summary
- Next Steps

Patient Safety is Non-Negotiable

Current environment is not conducive for patient safety

Complexity exists with current e-pedigree approach



- Requirement to establish an e-pedigree for each saleable unit makes the approach more complex
- Industry are concerned about their ability to meet the timelines ~ 5 to 7 years *1
- Concerns have been raised by one manufacturer over the cost to ensure compliance ~ $95 to $100 million *1
- The different technologies and approaches increase complexity for players in the supply chain *2
- No inference significantly increases complexity for all parties ("double cost"*2)

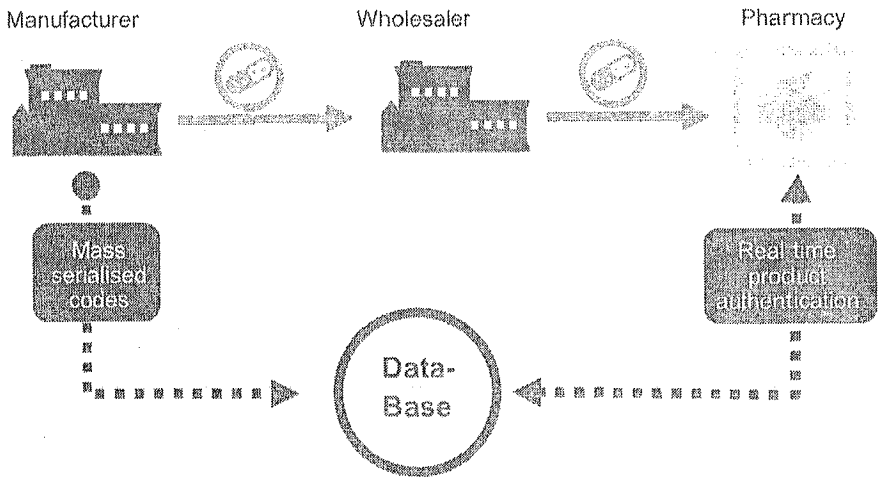
*1 Pfizer presentation to CEbP 20th Jun 07, *2 Walgreens presentation to CEbP 20th Jun 07

Authentication and case level e-pedigree can help

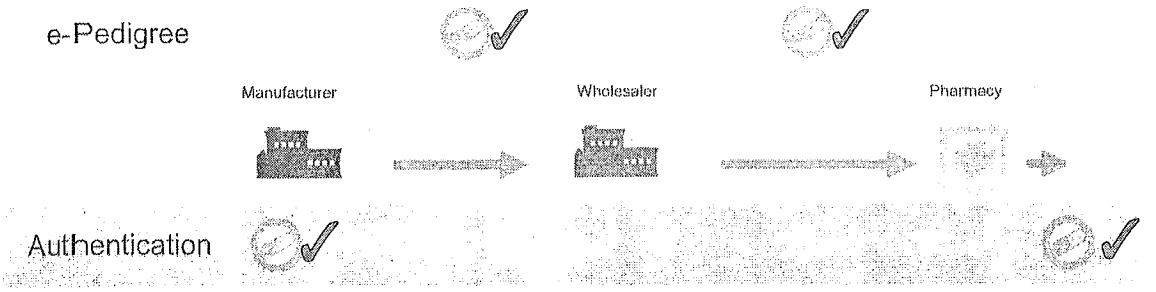
"Authentication is the process to verify at the point of dispense that the goods being dispensed have the same manufacturer's identifier displayed as present on the secure data base provided by the manufacturer"

- Authentication is complementary to the objectives of the California Board of Pharmacy and e.pedigree
- Authentication is focused on Patient Safety
- Authentication can enhance the e.pedigree objectives
- Authentication can simplify the complexity of e.pedigree
- Authentication could provide justification for inference from saleable unit to case level e-pedigree

Authentication: How does it work?



How can Authentication enhance case level e.pedigree?



e-Pedigree	Authentication at Point of Dispensing
Principle: Check at Each Step	Principle: Good Going In = Good Going Out
Requires involvement of whole supply chain	Relies on fewer parties in the supply chain
Complex to implement	Less complex to implement
Relies on integrity of previous record	Linked to dispensing activity
Requires consistent approach to maximise efficiency	Instant electronic recall notification
Requires the identification of product at each point in the supply chain	Expiry date notification
Focus on logistic integrity	**Focus on patient safety**

Aegate: Authentication progress across Europe

Belgium – market total of 5,300 pharmacies
- Launched in 2006
- Access to 70% of Belgian Pharmacies via 4 software providers
- Endorsement from Belgian Pharmacists Association

Greece – market total of 9,500 pharmacies
- Launched October 2007
- Access to 90% of Greek pharmacies via 4 software providers
- Close interaction with Pharmacist Groups

Italy – market total of 17,400 pharmacies
- To launch Q1 2008

18 major pharmaceutical companies, others joining
260 million unique ids in the system by year end
1,300,000 authentications per month by year end

Aegate pharmacist feedback

- " I find the information about the recalls and expiry dates very useful: it supports the existing information channels and increases trust and confidence when dispensing products"

- "Although initially I was afraid it would overload my system with messages; this is not the case. The messages that come in are valid. It makes it possible to quickly double check. At the end of the day, you as the pharmacist are the one who decides if, keeping the patient's health in mind, a product can be dispensed or not."

Proposed Californian approach

Principle

If the every saleable unit is Authenticated in the dispensary, then inference between case level and the saleable unit can be justified and the existing legislation can be met

Summary

Case level e.pedigree	+	Authentication at the point of dispense	+	Inference to saleable unit	=	Existing legislation can be met

What will it require?

- The **Californian Board of Pharmacy** needs to accept the principle of inference from case level to saleable unit provided it is supported by Authentication in the pharmacy
- The **Californian Board of Pharmacy** needs to endorse a coding standard (i.e. GS1)

Next Steps

- A decision is required from the California Board of Pharmacy regarding Inference and Authentication
- Suggest a Task Force is set up to evaluate this proposal and generate a road map. The working party should consist of:-
  - 2x Solution providers (of which one is Aegate)
  - 3x Manufacturers representatives
  - 2x Wholesaler representatives
  - 2x Pharmacy Chain representatives
  - 1x CBoP representative (observer)
- Tasked to report back and present a paper to the Board meeting on January 23rd 2008 detailing implementation timelines, requirements and benefits

Summary

- Authentication at the point of dispense is a viable, timely and complementary solution to improving Patient Safety by securing the supply chain and providing additional value to pharmacy
- Protects the pharmacists and patients
- Supports case level e-Pedigree

Authentication and case level e.pedigree can protect the patient and secure the supply chain

Thank You

Drug Pedigree Laws
Real World Applicability Of The Secondary Sector's Experience: Practical vs. Theoretical

Presented by
Gene Alley
Vice President – Regulatory Affairs

NCPD National Coalition of Pharmaceutical Distributors

NCPD

Independent Distributors Formed NCPD in June 2006

NCPD National Coalition of Pharmaceutical Distributors

- Open to all Prescription Drug Wholesalers
- Proactively addresses Pedigree/Rule issues related to independent/secondary distributors
- Members distribute to Physicians, Clinics, Pharmacies, Long Term Facilities, Dentists, etc.
- Demonstrates the Value Secondary Wholesalers provide

NCPD

What Value Do Secondary Wholesalers Provide?

- Personalized Customer Service
- Local Emergency Response
  - i.e., critical need due to disasters like recent CA fires
- Convenience
  - Time Savings
- Extended Terms
- Low minimums
- Competition
- Flexibility
  - Delivery, return policy, price adjustments

Who Do Small Distributors Benefit?

- End Users
  - Lower costs
- Pharmacies and Hospitals
  - Increased profits
- Large Distributors
  - Consolidate purchases from small accounts
- Manufacturers
  - Distribution options
- Local Communities
  - Employment

NCPD National Coalition of Pharmaceutical Distributors

NCPD supports measures that increase the security of the nation's pharmaceuticals, and urges California to involve all stakeholders in the pedigree implementation process.

NCPD Members.....

- Pedigree positions come from an applied perspective
- Have the most pedigree experience and understand the challenges of the paper pedigree system first hand
- Are willing to work with the CA BoP and other industry stakeholders to provide institutional knowledge on what has & hasn't worked
- Have seen first hand that paper pedigrees have been successful in increasing the security of the supply chain
- Want to be involved in pilot programs with other sectors of the industry
- Realize this is uncharted territory for the CA BoP and wish to be a "sounding board", a resource with practical experience in the day to day challenges of pedigree implementation

Surety Bond Inequities

- Surety Bonds disproportionately burdens the small distributors; any bond program should be flexible enough to reflect the economic realities associated with small businesses; one size doesn't fit all
- Annual revenue figures unrealistic to Medical Surgical Supply Distributors; product mix is usually 80% supplies and equipment and 20% drugs; therefore a $10MM company sells $2MM in Rx Drugs, but must buy a $100K bond vs. a $25K bond
- Multiple state bonds put small distributors at a competitive disadvantage; availability of bond is proportionate to company revenue
- Solution: One national surety bond proportionate to revenue (preferred), or a sliding-scale CA bond that is equitable to all

CA Pedigree:
Push On, Delay Entirely, Phase In?

- Patient Safety Must be The Primary Concern
- Serialization is a big problem; implementation by 01/09 will be challenging
- Pharmacies are dependent on manufacturers to determine what technology to buy, leaving little implementation time
- Pedigree with lot numbers has proven to be an extremely valuable tool in increasing the security of the supply chain
- Manufacturers are overlooking the ROI that electronic pedigree will provide them
- An electronic pedigree without serialization is better than no pedigree in California for another two years

NCPD Recommendations

- Patient Safety Must be THE Primary Concern
- Phased in approach is a must; legislation should be initiated to allow BoP flexibility it needs
- Implement Electronic Pedigree January 1, 2009 with same rules as in current statute
- Delay Serialization until 2011, and phase in on a risk-based strategy
- Make Surety Bond Equitable to ALL distributors
- Include NCPD as one of your many resources to help determine the best method to protect CA consumers

NO Pedigree in Force = CA Consumers Still at Risk

If you let the Perfect become the Enemy of the Good, NOTHING will ever be Accomplished

NCPD National Coalition of Pharmaceutical Distributors

gene.alley@ncpdusa.org

www.NCPDusa.org

Representing Independent Pharmaceutical Distributors

Gene Alley – Vice President Regulatory Affairs

About NCPD

The National Coalition of Pharmaceutical Distributors represents and promotes the value of small and independent pharmaceutical distributors with respect to legislatures, regulatory organizations, manufacturers, dispensers, and the community at large through rigorous advocacy in order to preserve the businesses of its members, to ensure distribution system efficiency and to uphold public safety.

www.NCPDusa.org

December 5, 2007

E-Pedigree Work Group
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

Ref: E-Pedigree compliance by January 2009

Good afternoon committee members and leadership.

My name is Jeff Schaengold and I am appearing on behalf of myself, as well as a business unit of the Siemens organization.

Siemens is a global leader in Health Sciences, Energy and Industry with global revenue approaching $200 Billion.

Siemens is either in a number 1 or number 2 global leadership positions in almost every business segment. Most particularly to this audience, Siemens is the world's largest health diagnostics company, one of the leading medical device supplier and a global leader in traceability and IT solutions for healthcare.

Personally, I've been leading the adoption of technologies such as EDI, barcode, RFID and eCommerce for close to 3 decades.

Committee members, I am here to respectfully suggest that all the elements presented to the committee and the State leadership to date, while well meaning, will result in delayed adoption of drug traceability without justifications. The delay beyond January 2009 will jeopardize the lives of Californians every single minute of the day.

What I would like to present to this committee is that traceability is 95% adoption of the serialization principle and 5% deciding on standards.

Committee members, traceability and serialization have existed in aviation, automotive, and electronics for over 70 years without a detrimental impact to the business.

The concept of serialization is not new and it's not expensive.

Serialization of drugs will cost a fraction of a cent per unit. To drug manufacturers the total cost impact of serialization is less than the cost of subsidy of a company cafeteria program.

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As to the application of a serial number to a drug package, the longest timeline element is equipping the packaging line with the appropriate equipment to print a serial number on the package. It doesn't matter what the structure of a serial number is determined. Serial number formats can be modified, literally, on the fly and older version serial numbers can be read until sunset and new formats can be backward compatible.

Logging serial number data to a server is as simple as logging any event on a company's data network.

Committee members, while standards for serial number formats and decisions of the use of barcode vs. character based vs. RFID for the conveyance of the serial number are beneficial, these factors can not impede adoption of serialization and ePedigree in the State of California.

To that end, Siemens and I are presenting to this committee our commitment to make the resources available to any drug manufacturer or wholesaler that needs to fast-track their package serialization and ePedigree solution to meet the January 2009 date.

With close to 500,000 employees worldwide, Siemens has the resources to provide the IT services and the packaging marking technologies to achieve the targets set for California ePedigree.

To qualify this position of support to the California State Board of Pharmacy, Siemens and I have been developing and leading the development of RFID for over 25 years.

Through acquisitions and internal development, Siemens is the inventor of the datamatrix code that is the default conveyance for machine readable serial number.

Siemens is the global leader in high speed processing of small articles and Siemens is capable of marking, reading and verifying products on a conveyor line faster and better than any company in the world.

Committee members, this is not a commercial for Siemens. This is an offer to Californians from Siemens to lead the improvement of the delivery of drugs to the 30 million citizens that are suffering today because of errors in dispensing drugs and counterfeit drugs.

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Look to other industries....

Recently, I was at a Wal-Mart in Connecticut. I purchased a printer. As the Wal-Mart clerk scanned the UPC code for the $25 printer, the POS screen prompted the clerk to scan the serial number.

Committee members, if Wal-Mart can train an entry level clerk to scan a serial number, it is beyond our comprehension that a healthcare delivery person can not be trained to do likewise. Do we perceive the retail clerk to be better trained than a healthcare provider?

A manufacturer of ink jet cartridges can serialize every one of the 100's of millions of cartridges they produce, and we can't serialize oncology drugs?

Fast food restaurants can afford to provide unit dose condiments with a $1.00 burger and we can't deliver unit dose packaging of $50 pills ?

We would like to help California draw a line in the sand, committee members, and support the January, 2009 life saving requirement for ePedigree.

As I mentioned earlier, we are ready, willing and able to support any drug producer and wholesaler be compliant with serializing drugs sold in California by January 2009.

There are no caveats in our statement. We are not providing grandfather exceptions or waivers. Siemens is supporting the initiative to have 100% of the drugs sold in California January 2009 serialized and ePedigree ready and we are making the resources available to accomplish the tasks.

Thank you for the opportunity to present our message.

Jeff Schaengold
Traceability Internal Consultant
Siemens Energy & Automation

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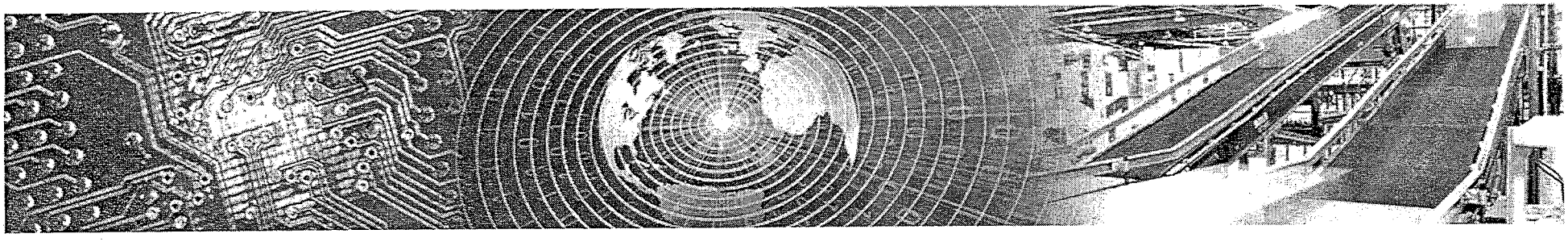
Attachment 2

EPCglobal's Presentation on Inference, Given December 5, 2007



Inference Discussion

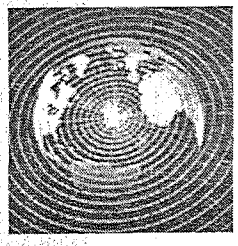
Excerpt from the
EPCglobal HLS Industry Adoption Roadmap
Final Version v13.1

Prepared by the EPCglobal HLS Industry Adoption Task Force

For General Release

Published ___, 2007

EPCglobal



Appendix 1
Suggestions: Serialized Inference

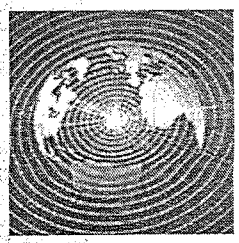
Business Problem:

- California SB1476 at Section 4034(b)(3) requires the "name and address of each person certifying delivery or receipt".
- This 'certification' of item-level serial numbers presents new challenges:
  - Line of sight technology would result in opening every case and scanning every item within, since the item serial numbers are not visible.
  - Non-line of sight technology, if less than 100% of the items were read, would result in opening every case and scanning every item within.
  - Opening cases at time of receipt introduces new risks, is time-consuming, and adds costs into supply chain operations.

One Potential Suggestion:

- Inference is one of many mechanisms to enable trading partners to leverage strong supply chain practices to meet these challenges.
- Adoption of any solution to these challenges remains an individual company decision.
- The California BOP has scheduled working sessions with industry to better understand these challenges. Regulatory guidance may result from these working sessions.

EPCglobal



IATF Companies / Organizations

The following organizations participated in creation of this deliverable.

Supply Chain Partners

- Abbott Laboratories
- Ahold N.V.
- Albertsons
- Alcon Laboratories
- Allergan
- AmerisourceBergen Corp.
- AstraZeneca
- Baxter Healthcare Corp.
- Bristol Meyers Squibb
- Cardinal Health
- CVS
- Dai Nippon Printing
- Genzyme Corporation
- GlaxoSmithKline
- Johnson & Johnson
- Ken Traub Consulting LLC

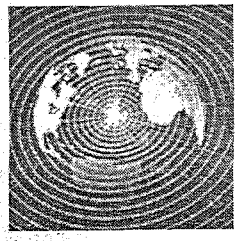
Supply Chain Partners

- Kimberly-Clark
- Matsushita Electric
- McKesson Corporation
- Merck & Co.
- MetaBiz
- Motorola Inc.
- NEC Corporation
- Nestle S.A.
- Pfizer Inc.
- Proctor & Gamble
- Royal Philips Electronics N.V.
- Target
- The Dow Chemical Company
- Unisys
- Upsher-Smith Labs
- Walgreens Company

Trade / Regulatory

- Auto-ID Labs (MIT)
- CPhA
- FDA
- HDMA
- NACDS
- NCPA
- GS1 Healthcare
  - EPCglobal HLS Community
  - GS1 HUG Community

EPCglobal

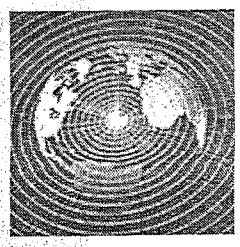


Appendix 1
Suggestions: Serialized Inference Definitions

- Infer (Inference): Conclude from evidence (Webster's Dictionary).
- Working Definition: To infer the serialized number based on information provided by the upstream supply chain, reasonable inspection of the product, and application of the Serialized Inference Rule by the Shipping and Receiving partners.
- Serialized Inference Rule: The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. A Serialized Inference Rule should be defined for each packaging unit (e.g., pallet, case, item, etc.) for the key process steps of Commission/Aggregation, Ship, and Receipt.

Enhance Patient Safety in the supply chain by allowing supply chain partners to leverage the good business practices initiated by manufacturers which are then continued through the supply chain by downstream trading partners.

EPCglobal

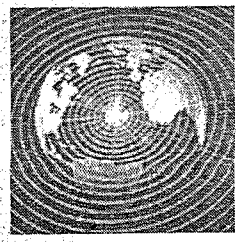


Appendix 1
Suggestions: Serialized Inference

Assumes that each Trading Partner follows good business practices, such as:

- Good manufacturing and good distribution practices.
- Documented controls and Standard Operating Procedures.
- Captures quality metrics to minimize "defects" of inbound and outbound product.
- When process errors are detected, implements changes to those processes to prevent future errors.
- Processes are periodically reviewed for improvement opportunities.

EPCglobal



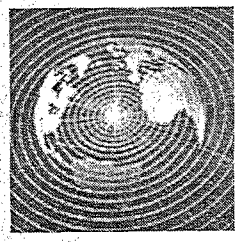
Appendix 1
Suggestions: Serialized Inference

To summarize, Serialized Inference is possible when the following conditions have been achieved:

- A collection (item, full or mixed case, tote, pallet, etc.) is present.
- The collection is identified with a unique serial number, and each member of the collection (item, case, tote, pallet) is also identified with a unique serial number.
- The receiving trading partner receives an electronic communication containing the serialized numbers and the hierarchical relationship of those serialized numbers within the collection.
- The receiving trading partner must have assurance that the collection has remained intact since leaving the last trading partner.
  - If the receiving trading partner has reason to believe that the collection has not remained intact since leaving the last trading partner, then inference should not be used.

These inference suggestions are intended to provide each trading partner with an understanding of how inference can be used by all the various supply chain participants. The application of inference remains an individual business decision.

EPCglobal



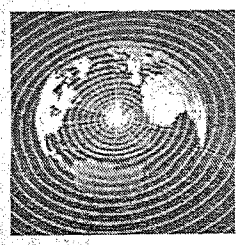
Appendix 1
Suggestions: Serialized Inference

Designed for transactions between trading partners, however can be applied to intra-company transactions as well.

Serialized Inference Scenarios:

- Single Item Commission
  - Apply serial number to one single Item.
- Item into Case Commission/Aggregation
  - Apply serial number to Case and build item-to-case hierarchy.
- Case to Pallet Commission/Aggregation
  - Apply serial number to a homogenous pallet comprised of Cases of all one product and build case-to-pallet hierarchy.
  - May be a full pallet or a partial pallet.
- Tote or Mixed Case Commission/Aggregation
  - Apply serial number to Case or Tote containing either a mixture of SKU's or 1 or more items of a single SKU, and build item-to-case hierarchy. Typically conducted as part of a pick/pack/ship operation.
- Mixed Pallet Commission/Aggregation
  - Apply serial number to Pallet of mixed Cases or Totes, and build case-to-pallet or tote-to-pallet hierarchy. Pallet could contain mixed cases and/or full cases. The full cases could be from one product or from multiple products.

EPCglobal



Appendix 1
Suggestions: Serialized Inference

Designed for transactions between trading partners, however can be applied to intra-company transactions as well.

Serialized Inference Scenarios:

- Shipments
  - Single Item Shipment (one single item shipped)
  - Case Shipment (all one item)
  - Tote or Mixed Case Shipment (One or more items or mixed items, typically part of a pick/pack/ship operation)
  - Pallet Shipment (all one item on a pallet)
  - Mixed Pallet Shipment (mixed items on a pallet)

- Receipts
  - Single Item Receipt (one single item received)
  - Case Receipt (all one item)
  - Tote or Mixed Case Receipt (One or more items or mixed items, typically conducted as part of a pick/pack/ship operation)
  - Pallet Receipt (all one item on a pallet)
  - Mixed Pallet Receipt (mixed items on a pallet)

Shipments and Receipts of pallet, case, mixed case, and tote assumes the hierarchy and packaging integrity remained intact from the Commission/Aggregation process.

EPCglobal

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Implementation Submission Statement Template

The California State Board of Pharmacy is interested in developing agendas and discussion items for the E-Pedigree Work Group Meetings around items with value to the industry.

Please use the following template headings to provide a description of issues, problems or preferred solutions on implementation issues involving California's electronic pedigree requirements. These statements should be submitted to the board in advance of an E-Pedigree meeting, conforming to the template below:

- Issue/Topic: *Inference*
- Submitted by: *Robert Celeste, Director, Healthcare, EPCglobal North America*
- Background: Historical overview/framework of current practices in the industry, what are the different scenarios in which this practice or subject area has arisen already, what are the processes employed to date, what members of the supply chain are involved? *EPCglobal North America would like to submit the attached presentation on "Inference" to provide a base level of understanding on the subject. EPCglobal's Industry Adoption Task Force recently concluded a body of work that contained general material on inference. That document has been widely distributed to healthcare companies and associations. It is our hope that the material will form a basis for discussion by companies and trade organizations for their point of view on the subject.*
- Challenge presented by timely compliance with California's law:
- Frequency or prevalence of this practice or subject area: *Our understanding through requirements and Use Case development with the industry, is that a fair amount of inference is used by trading partners today.*
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- A specific discussion of the costs of such implementation, on as many variables as possible (per-unit, per-store, per-facility, per-company) *Our hope is that this information will be useful by companies and associations in developing their specific inference scenarios and costs .*
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- Desired solution:
- Without the desired solution, what is the potential impact?

- Contact information and date: *Robert Celeste, Director, Healthcare, EPCglobal North America. November 21, 2007.*
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Note: it is anticipated that these presentations will come, at least initially, from industry associations or other representative associations, so as to capture larger quantities of data or experience and focus the discussions on systemic rather than individual solutions. It is also anticipated that competing concerns of different industry players may need to be suspended to advance the presentations.

Please submit to Virginia Herold at the above address. Thank you.